BC-3000 Plus

Auto Hematology Analyzer

Operation Manual

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1 Using This Manual

1.1 Introduction

This chapter explains how to use your BC-3000 Plus operation manual, which is shipped with your BC-3000 Plus hematology analyzer and contains reference information about the BC-3000 Plus and procedures for operating, troubleshooting and maintaining the analyzer. Read this manual carefully before operating your analyzer and operate your analyzer strictly as instructed in this manual.

NOTE

- **Be sure to operate your analyzer strictly as instructed in this manual.**

1.2 Who Should Read This Manual

This manual contains information written for clinical laboratory professionals to:

- learn about the BC-3000 Plus hardware and software;
- customize system settings;
- perform daily operating tasks;
- perform system maintenance and troubleshooting.

1.3 How to Find Information

This operation manual comprises 11 chapters and 4 appendices. Refer to the table below to find the information you need.

If you want to …	See …
learn about the intended use and parameters of the BC-3000 Plus	**Chapter 2 Understanding Your Analyzer**
learn about the hardware and software of the BC-3000 Plus	**Chapter 2 Understanding Your Analyzer**
learn about how the BC-3000 Plus works	**Chapter 3 Understanding the System Principles**
learn about how to install the BC-3000 Plus	**Chapter 4 Installing Your Analyzer**
learn about how to define/adjust system settings	**Chapter 5 Customizing the Analyzer Software**
learn about how to use the BC-3000 Plus to perform your daily operating tasks	**Chapter 6 Operating Your Analyzer**
learn about how to review the saved analysis results	**Chapter 7 Reviewing Sample Results**
learn about how to use the quality control programs	**Chapter 8 Using the QC Programs**
learn about how to calibrate the BC-3000 Plus	**Chapter 9 Using the Calibration Programs**
learn about how to maintain/service the BC-3000 Plus	**Chapter 10 Maintaining Your Analyzer**
learn about the meanings of the error messages and how to correct the problems	**Chapter 11 Troubleshooting Your Analyzer**
learn about the technical specifications of the BC-3000 Plus	**Appendix B Specifications**
see the summary of all safety messages included in this manual	**Appendix C Precautions, Limitations and Hazards**
learn about the communication protocol of the BC-3000 Plus	**Appendix D Communication**

1.4 Conventions Used in This Manual

This manual uses certain typographical conventions to clarify meaning in the text:

- All capital letters enclosed in [ ] indicate a key name (either on the built-in keypad or the external keyboard), such as [ENTER].
- All capital, bold and italic letters indicate a special operation defined in the following section, such as ***SELECT***.
- Bold letters included in " " indicate text you can find on the screen, such as "**Prepare to ship**".
- Bold letters indicate defined screen areas/fields, such as **System Status** area, or chapter titles, such as **Chapter 1 Using This Manual**.

All illustrations in this manual are provided as examples only. They may not necessarily reflect your analyzer setup or data displayed.

1.5 Special Terms Used in This Manual

When you read …	It means …
CLICK	to press the arrow keys ([←][→] [↑][↓]) as needed to move the cursor to a certain software button on screen and press [ENTER].
ENTER	■ to press the arrow keys ([←][→] [↑][↓]) as needed to move cursor to the desired edit box and use the built-in keypad or the external keyboard to enter the desired characters or digits. Note that besides the numeric keys you may also use the [PgUp] or [PgDn] keys to enter digits; or ■ to scan the number in using the bar-code scanner.
DELETE	to press the arrow keys ([←][→] [↑][↓]) as needed to move the cursor to the character or digit to the left of the one you want to delete and press [DEL]; or to press the arrow keys ([←][→][↑][↓]) as needed to move the cursor to the character or digit to the right of the one you want to delete and press [BackSpace] on the external keyboard.
MODIFY	to move the cursor to the character or digit you want to change and re-enter the desired one using either the built-in keypad or the external keyboard.
SELECT from " ** " pull-down list	to press the arrow keys ([←][→] [↑][↓]) as needed to move the cursor to the desired edit box and press [ENTER] to display the pull-down list and press [↑] or [↓] to move the cursor to the desired item and press [ENTER] to select it.
SELECT	to press the arrow keys ([←][→] [↑][↓]) as needed to the desired item and press [ENTER].

NOTE

- **This analyzer adopts a fixed decimal point. You can enter the digits without bothering to look for the [.] on the external keyboard.**

1.6 Symbols

You will find the following symbols in this manual.

When you see…	Then…
⚠ WARNING	read the statement below the symbol. The statement is alerting you to an operating hazard that can cause personnel injury.
⚠ CAUTION	read the statement below the symbol. The statement is alerting you to a possibility of analyzer damage or unreliable analysis results.
NOTE	read the statement below the symbol. The statement is alerting you to information that requires your attention.
	read the statement below the symbol . The statement is alerting you to a potentially biohazardous condition.

You may find the following symbols on the analyzer or the reagents.

When you see…	It means…
	EQUIPOTENTIALITY
	CAUTION, CONSULT ACCOMPANYING DOCUMENTS.
	BIOLOGICAL RISK
	HIGH VOLTAGE
	ALTERNATING CURRENT
IVD	FOR IN VITRO DIAGNOSTIC USE

	BATCH CODE
	USE BY
	SERIAL NUMBER
	DATE OF MANUFACTURE
	TEMPERATURE LIMITATION
	CONSULT INSTRUCTIONS FOR USE
	THE DEVICE IS FULLY CONFORMANCE WITH THE COUNCIL DIRECTIVE CONCERNING IN VITRO DIAGNOSTIC MEDICAL DEVICES 98/79/EC.
	MANUFACTURER
	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
	IRRITATING SUBSTANCE
	THE FOLLOWING DEFINITION OF THE WEEE LABEL APPLIES TO EU MEMBER STATES ONLY: THE USE OF THIS SYMBOL INDICATES THAT THIS PRODUCT SHOULD NOT BE TREATED AS HOUSEHOLD WASTE. BY ENSURING THAT THIS PRODUCT IS DISPOSED OF CORRECTLY, YOU WILL HELP PREVENT BRINGING POTENTIAL NEGATIVE CONSEQUENCES

	TO THE ENVIRONMENT AND HUMAN HEALTH. FOR MORE DETAILED INFORMATION WITH REGARD TO RETURNING AND RECYCLING THIS PRODUCT, PLEASE CONSULT THE DISTRIBUTOR FROM WHOM YOU PURCHASED THE PRODUCT.

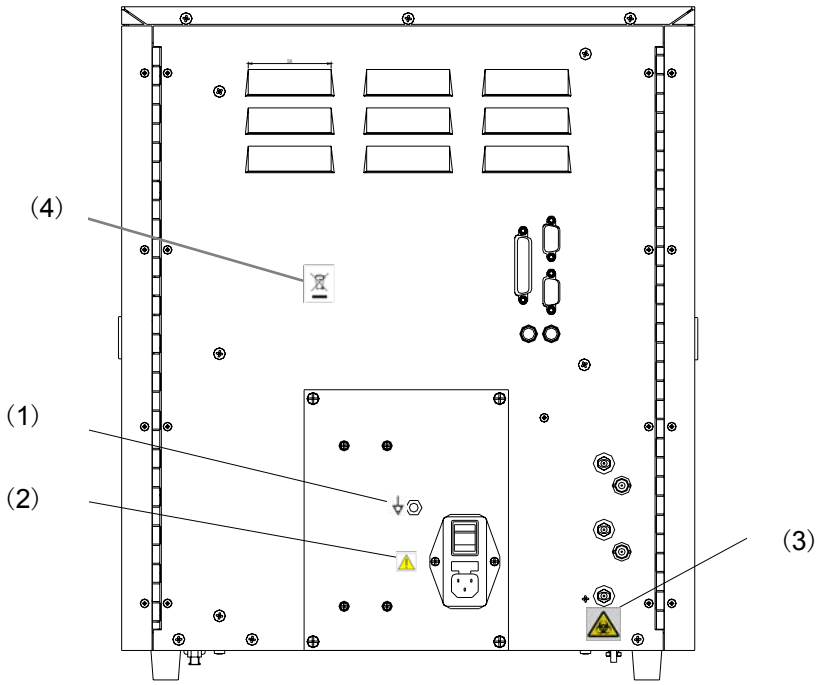


Figure1-1 Back of the Analyzer

(1)

Equipotentiality.

(2)

- Connect only to a properly earth grounded outlet;
- To avoid electric shock, disconnect power cord prior to removing or replacing fuse;
- Replace fuse only with the type and rating specified.

(3)

Biological risk.

(4)

The following definition of the WEEE label applies to EU member states only: The use of this symbol indicates that this product should not be treated as household waste. By ensuring that this product is disposed of correctly, you will help prevent bringing potential negative

consequences to the environment and human health. For more detailed information with regard to returning and recycling this product, please consult the distributor from whom you purchased the product.

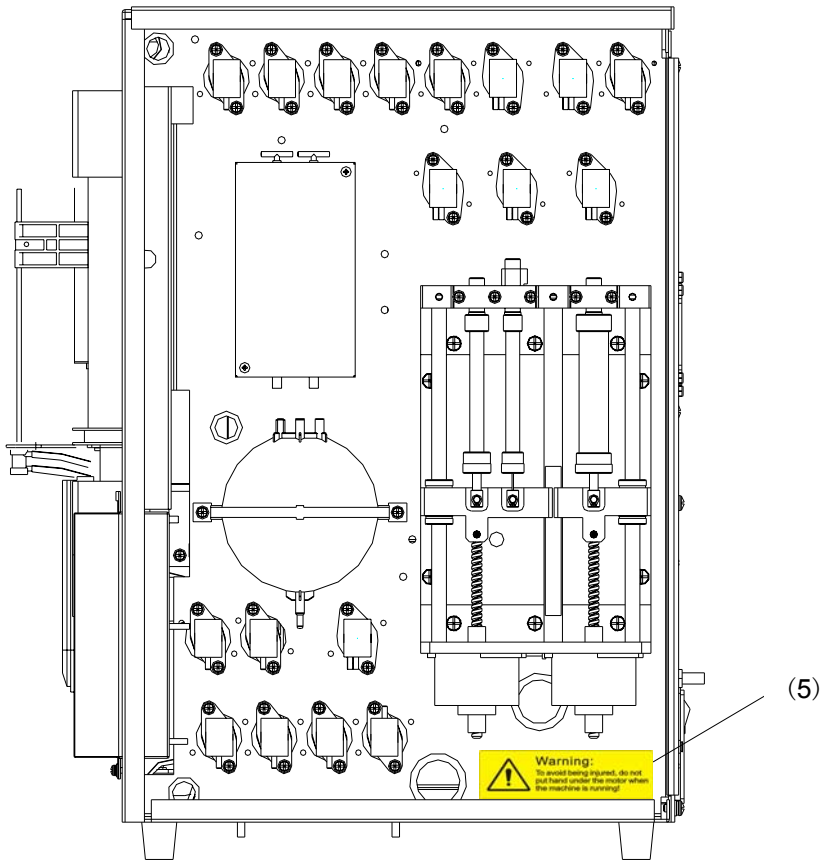


Figure1-2 Inside right of the analyzer

（5）

To avoid being injured, do not put hand under the motor when the machine is running.

2 Understanding Your Analyzer

2.1 Introduction

The BC-3000 Plus auto hematology analyzer is a quantitative, automated hematology analyzer and leukocyte differential counter for In Vitro Diagnostic Use in clinical laboratories.

2.2 Intended Use

NOTE

- **The purpose of this analyzer is to identify the normal patient, with all normal system-generated parameters, and to flag or identify patient results that require additional studies.**

The analyzer is used for the quantitative determination of the following 19 parameters and 3 histograms of blood samples.

White Blood Cell or leukocyte	WBC
Lymphocyte	Lymph#
Mid-sized cell	Mid#
Granulocyte	Gran#
Lymphocyte percentage	Lymph%
Mid-sized cell percentage	Mid%
Granulocyte percentage	Gran%
Red Blood Cell or erythrocyte	RBC
Hemoglobin Concentration	HGB
Mean Corpuscular (erythrocyte) Volume	MCV
Mean Cell (erythrocyte) Hemoglobin	MCH
Mean Cell (erythrocyte) Hemoglobin Concentration	MCHC
Red Blood Cell (erythrocyte) Distribution Width Coefficient of Variation	RDW-CV
Red Blood Cell (erythrocyte) Distribution Width Standard Deviation	RDW-SD
Hematocrit	HCT
Platelet	PLT
Mean Platelet Volume	MPV
Platelet Distribution Width	PDW*
Plateletcrit	PCT*
White Blood Cell Histogram	WBC Histogram
Red Blood Cell Histogram	RBC Histogram
Platelet Histogram	PLT Histogram

2.3 User Interfaces

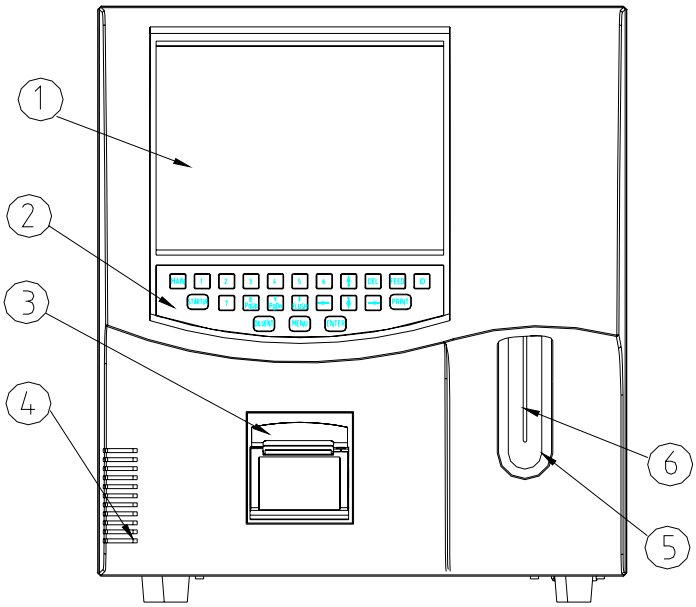


Figure2-1 Front view

1 ---- LCD

2 ---- Keypad

3 ---- Recorder

4 ---- Power indicator

5 ---- Aspirate key

6 ---- Sample probe

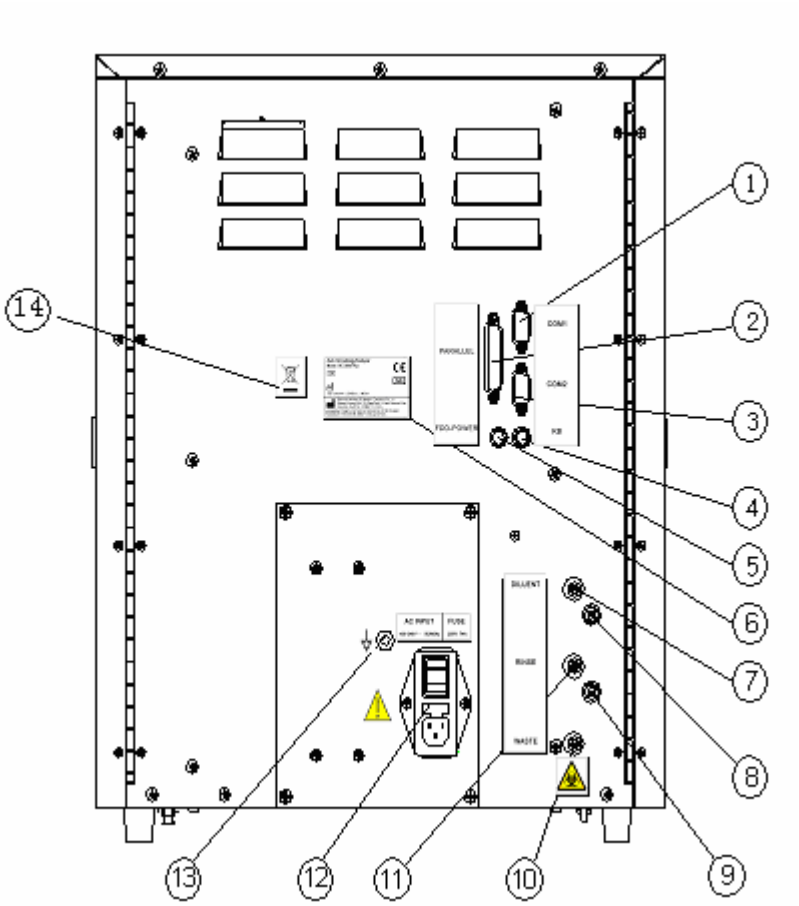


Figure2-2 Back view

1 --- RS-232 Port1
2 --- Parallel Port
3 --- RS-232 Port2
4 --- Keyboard interface
5 --- Power Interface of Floppy Disk Drive
6 --- Safety labeling
7 --- Diluent inlet
8 --- Diluent sensor connector
9 --- Rinse sensor connector
10 --- Waste outlet
11 --- Rinse inlet
12--- Power switch
13--- Equipotentiality
14--- WEEE labeling

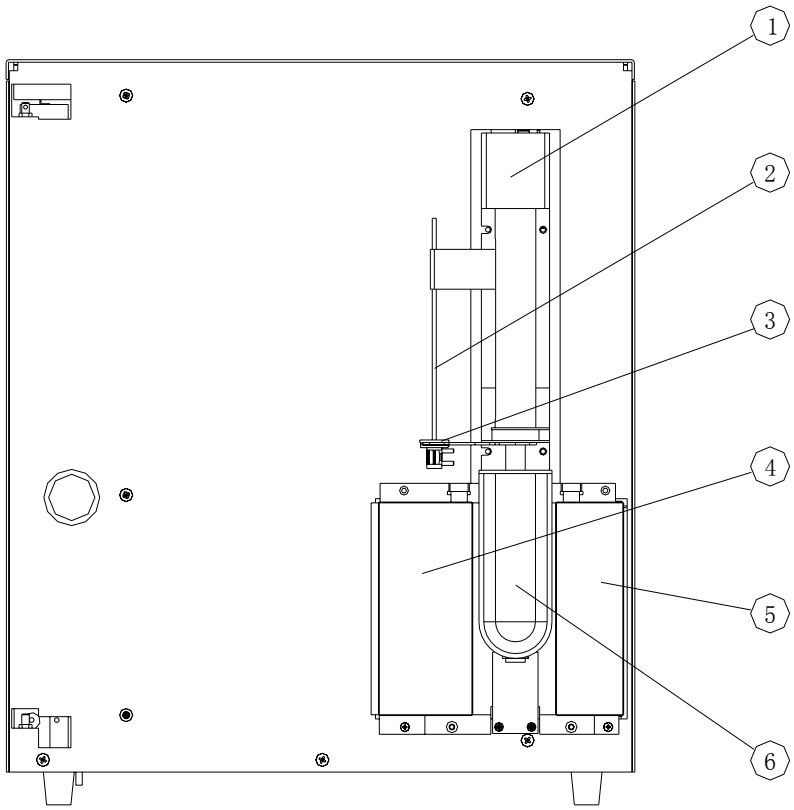


Figure2-3 Inside front of the analyzer

1 --- Elevator motor
2 --- Sample probe
3 --- Probe wipe
4 --- WBC shielding box
5 --- RBC shielding box
6 --- Aspirate key

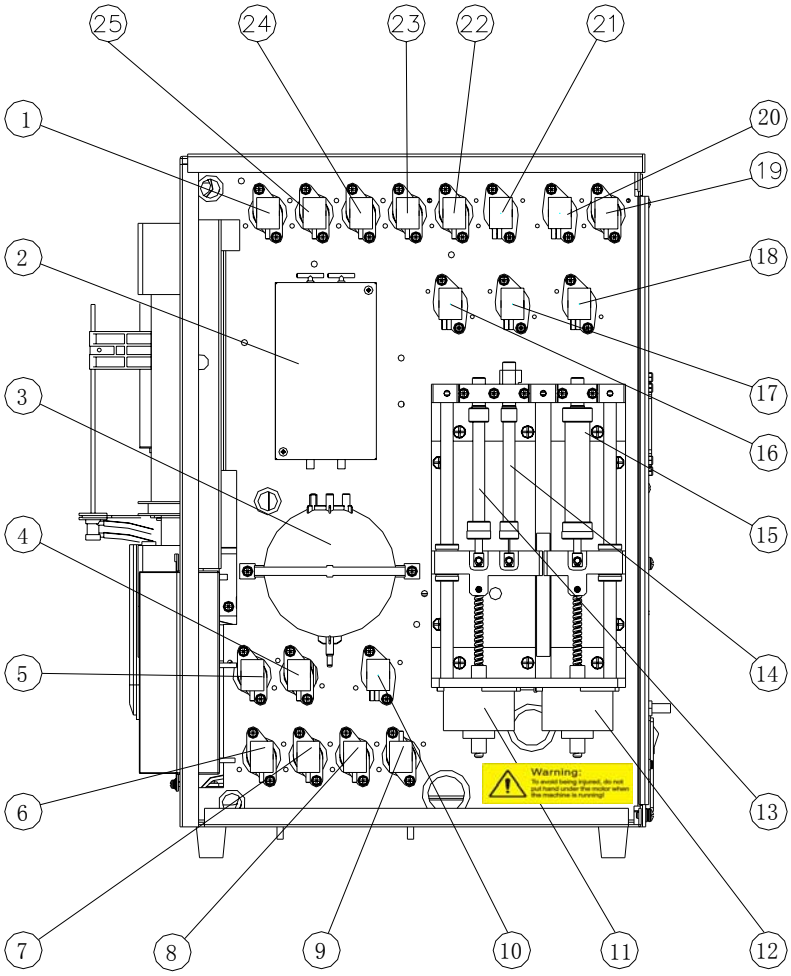


Figure2-4 Inside right of the analyzer

1 --- Valve8
2 --- Volumetric metering unit
3 --- Vacuum chamber
4 --- Valve13
5 --- Valve14
6 --- Valve12
7 --- Valve11
8 --- Valve10
9 --- Valve2
10 --- Valve9
11 --- 50ul and 2.5ml motor
12 --- 10ml motor
13 --- 2.5ml syringe
14 --- 50ul syringe
15 --- 10ml syringe
16 --- Valve6
17 --- Valve4
18 --- Valve3
19 --- Valve1
20 --- Valve5
21 --- Valve15
22 --- Valve16
23 --- Valve17
24 --- Valve7
25 --- Valve18

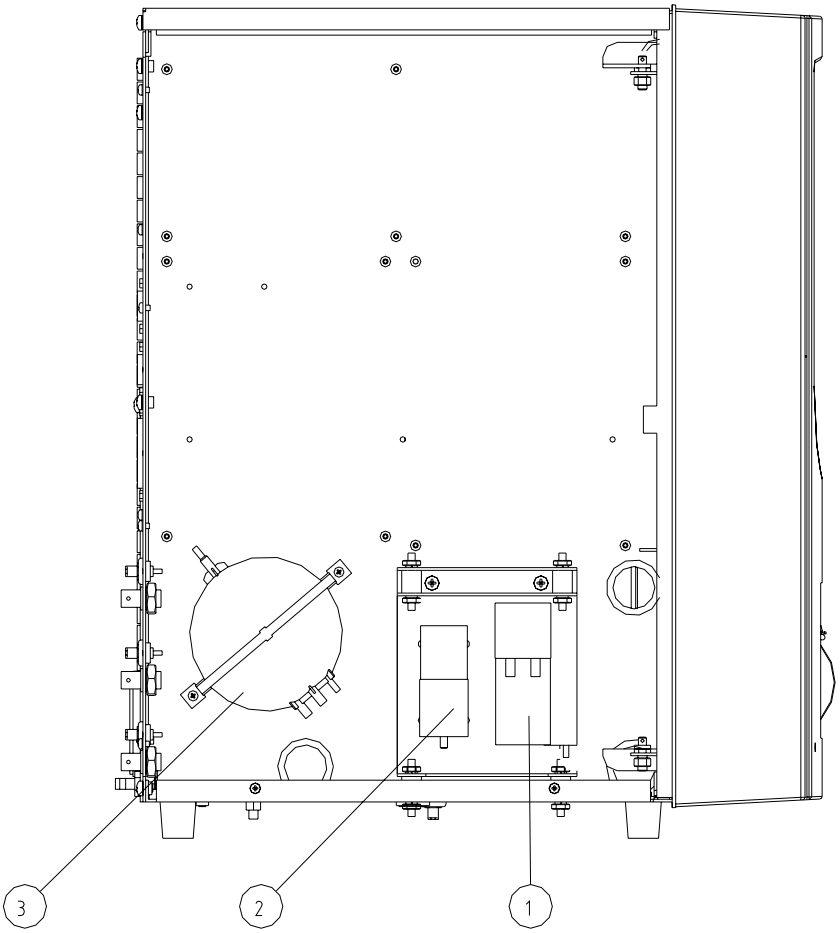


Figure2-5 Inside left of the analyzer

1 --- Fluid pump
2 --- Gas pump
3 --- Pressure chamber

2.3.1 LCD

The LCD is located on the front panel of the analyzer. It displays all alphanumeric and graphic data.

2.3.2 Input Devices

The input devices include the aspirate key, built-in keypad and PS/2 keyboard.

- Aspirate key

The aspirate key is located behind the sample probe, as Figure2-6 shows. You can press the key to start the selected run cycle or dispense diluent.

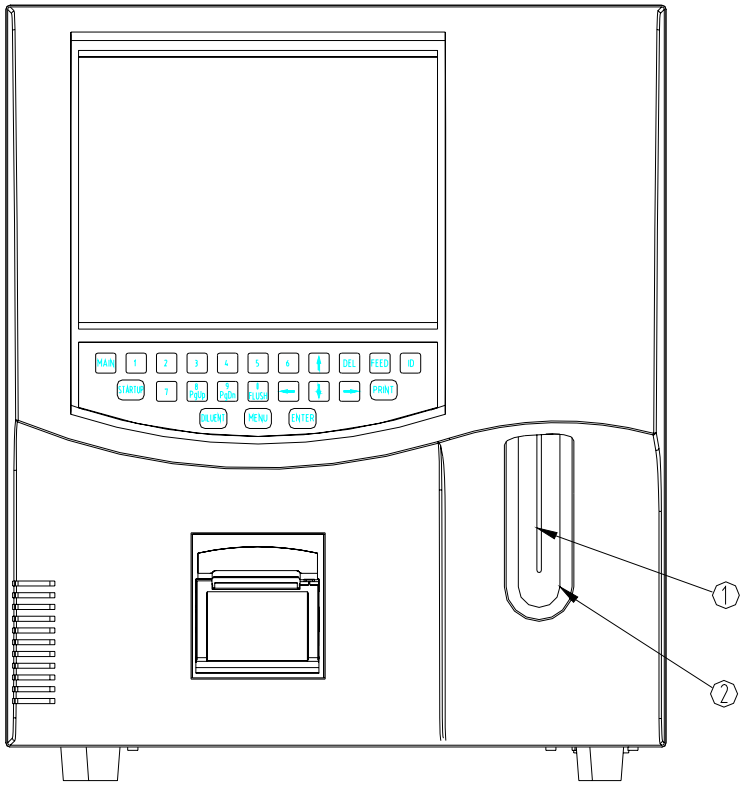


Figure2-6 Sample probe and aspirate key

1.Sample Probe 2. Aspirate Key

■ Built-in keypad

The 23-key keypad is located below the LCD, as Figure2-7 shows.

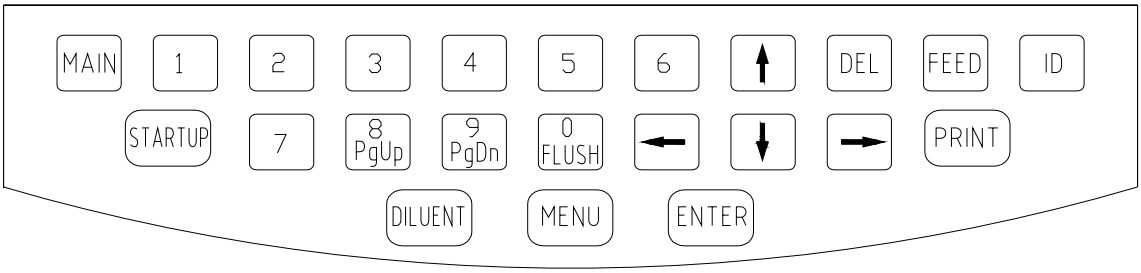


Figure2-7 Built-in keypad

■ PS/2 keyboard

The analyzer can also be controlled by an external PS/2 keyboard that should be connected to the analyzer's keyboard interface. See the table below for the correspondence between the keypad keys and the keyboard keys and for their functions.

Keypad	**PS/2 keyboard**	**Function**
[MENU]	[Esc]	To enter/exit the system menu.
[PRINT]	[P]or [p]	To print out data by the recorder or printer.
[DEL]	[Delete] or [Del]	To delete data and characters.
[ENTER]	[Enter]	To confirm or execute an operation.
[↑][↓][←][→]	[↑][↓][←][→]	To move the cursor.
[0]...[9]	[0]...[9]	To enter digits.
[PgUp][PgDn]	[PageUp] [PageDown]	To scroll screen.
[Flush]	/	To unclog the apertures.
[FEED]	/	To advance the recorder paper.
[MAIN]	/	To go back to the "**Count**" screen.
[DILUENT]	[D]or [d]	To enter the dispensing diluent state.
[STARTUP]	/	To execute the startup procedure (flushing the fluidic lines and checking background).
[ID]	[I]or [i]	To call out the screen to enter patient information.
/	Alphanumeric keys and other function keys.	To enter alphanumeric data or initiate a function.

2.3.3 Recorder

The thermal recorder is located on the front panel. You can use it to print out analysis reports and other interested information.

2.3.4 Keyboard Interface

A PS/2 keyboard can be connected here.

2.3.5 Serial Ports

The analyzer provides two RS-232 ports, one for connecting the scanner and the other for connecting a computer (host).

2.3.6 Parallel Port

The analyzer provides a parallel port to connect a printer or a floppy disk drive (a floppy disk drive is needed to upgrade the system software; the drive can only be connected by a Mindray-supplied cable).

2.3.7 Power Supply for the Floppy Disk Drive

It supplies power to the connected floppy disk drive. Only the drive power cable supplied by Mindray can be used.

2.3.8 Power Indicator

The power indicator tells you whether the analyzer is on, off or in the screen saver mode.

2.3.9 Printer（Optional）

An external printer can be connected to the parallel port at the back of the analyzer. You can use it to print out a detailed report and other interested information.

2.3.10 Scanner（Optional）

A bar-code scanner can be connected to the RS-232 port 1 of the analyzer. You can use it to scan the bar-coded sample IDs into the analyzer.

NOTE

- **Be sure to use the printer and/or scanner of the specified model.**

2.4 Instrument Software

2.4.1 Main Screen

After finishing the startup procedure, the analyzer enters the "**Count**" screen, which is the screen to be used most frequently, hence the name "Main screen". The main screen is shown in Figure2-8.

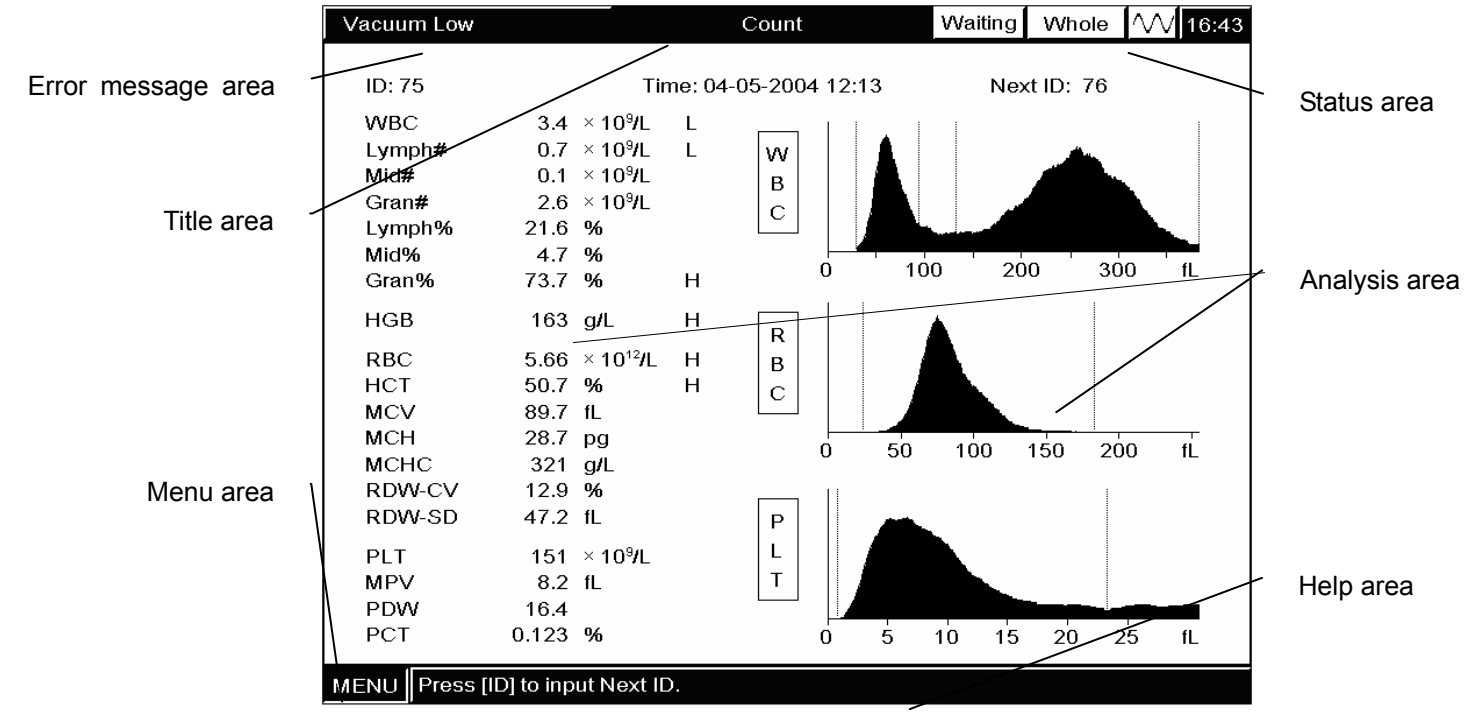


Figure2-8 "Count" screen

Error Message Area

The **Error Message** area displays error messages one by one, alternating every two seconds.

Title Area

The **Title** area displays the title of the current screen, which, in case of Figure2-8, is "**Count**"**.**

Status Area

- System Status Area

The **System Status** area displays whether this analyzer is ready for the next analysis. When it displays "**Ready**", it means this analyzer is ready and you can proceed to analyze the next sample. When it displays "**Waiting**", it means the analyzer is not ready for the next run yet. When it displays "**Running**", it means this analyzer is analyzing a sample.

- Count Mode Area

The **Count Mode** area displays in which analysis (count) mode, whole blood or prediluted, the next sample is to be analyzed.

- Transmission status

A live animation is displayed in this area when the transmission is in process.

- System Time Area

The **System Time** area displays the system time (in the 24-hour format).

Analysis Result Area

The **Analysis Result** area displays the analysis result, including sample ID, analysis time of the current sample.

Menu Area

When you press [MENU], this area displays the system menu.

Help Area

The **Help** area reminds you how to proceed to the next step.

2.4.2 System Menu

Press the [MENU] button and the system menu, shown in the figure below, will pop up.

Figure2-9 System menu

The system menu contains 9 programs. The programs followed by "▶"s have further sub-menus. See the figure below for the fully expanded menu.

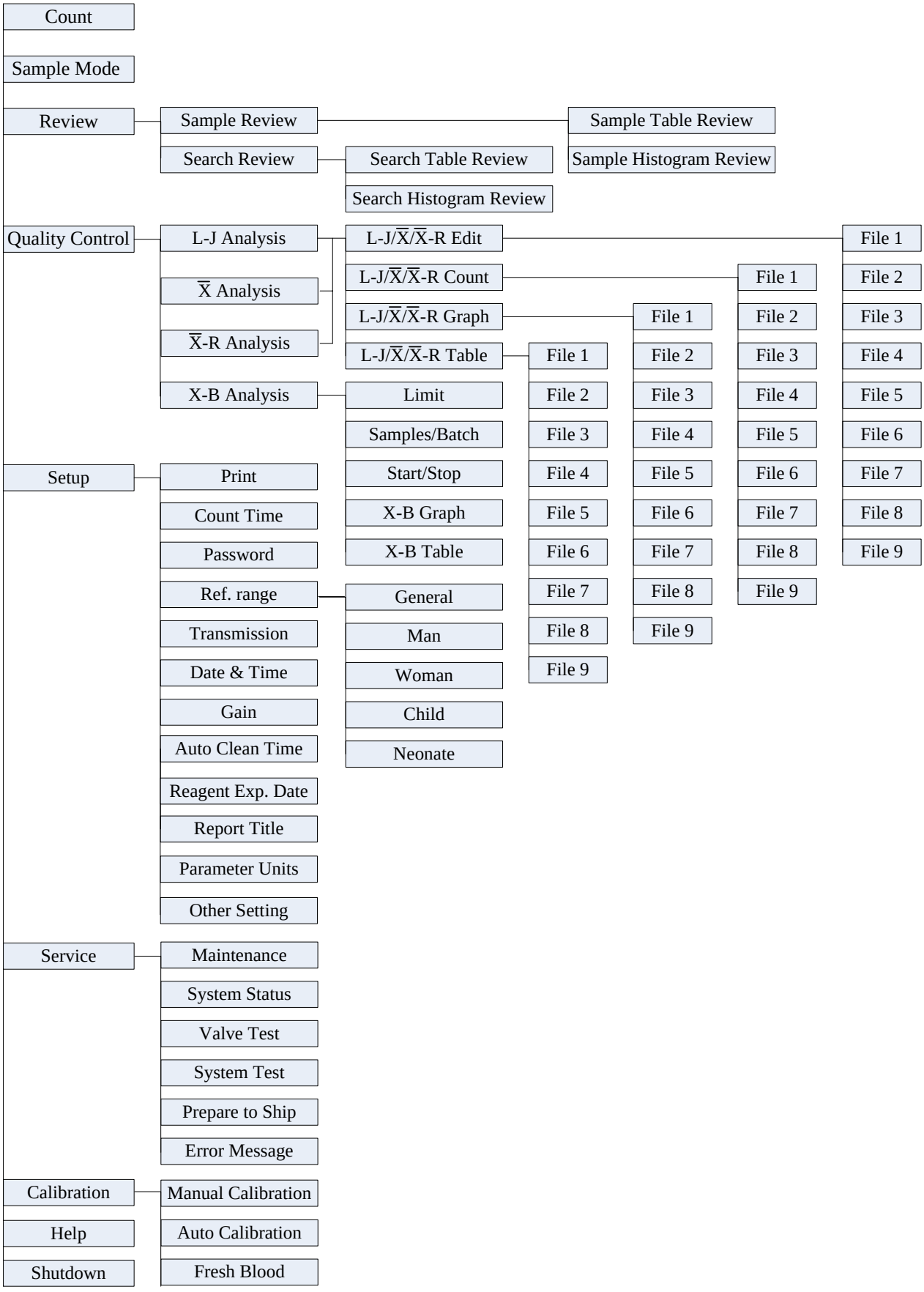


Figure 2-10 Fully expanded system menu

You can select the desired program as instructed below.

If you want to…	Select…
analyze samples	**Count**
select an appropriate analysis mode	**Sample Mode**
review sample results	**Review**
run the QC program	**Quality Control**
customize system software	**Setup**
maintain/service the analyzer	**Service**
calibrate the analyzer	**Calibration**
look for help	**Help**
shut down the analyzer	**Shutdown**

2.5 Reagents, Controls and Calibrators

Because the analyzer, reagents (diluent, rinse, lyse, probe cleanser and E-Z cleanser), controls, and calibrators are components of a system, performance of the system depends on the combined integrity of all components. You should only use the Mindray-specified reagents (see Appendix B Specifications), which are formulated specifically for the fluidic system of your analyzer in order to provide optimal system performance. Do not use the analyzer with reagents from multiple suppliers. In such use, the analyzer may not meet the performance specified in this manual and may provide unreliable results. All references related to reagents in this manual refer to the reagents specifically formulated for this analyzer.

Each reagent package must be examined before use. Inspect the package for signs of leakage or moisture. Product integrity may be compromised in packages that have been damaged. If there is evidence of leakage or improper handling, do not use the reagent.

NOTE

- **Store and use the reagents as instructed by instructions for use of the reagents.**
- **When you have changed the diluent, rinse or lyse, run a background to see if the results meet the requirement.**
- **Pay attention to the expiration dates and open-container stability days of all the reagents. Be sure not to use expired reagents.**
- **After installing a new container of reagents, keep the reagents still for a while before using them.**

2.5.1 Diluent

The diluent is formulated to meet the following requirements:

- To dilute the blood samples;
- To provide the blood cells with an environment similar to the blood plasma;
- To maintain the cell volume of each red blood cell and platelet during the count and sizing portion of the measurement cycle;
- To provide a conductive medium for impedance counting of white and red blood cells and platelets.

2.5.2 Lyse

The lyse is formulated to meet the following requirements:

- To rapidly break down red blood cell walls, release the hemoglobin from the cell, and reduce the size of cellular debris to a level that does not interfere with white blood cell counting.
- To convert hemoglobin to a complex whose absorbance is determined by the hemoglobin concentration.

2.5.3 Rinse

The rinse is formulated to rinse the baths and metering tubes and to provide proper meniscus formation in the metering tubes and maintain it during each measurement cycle.

2.5.4 E-Z Cleanser

The E-Z (enzymatic) cleaner is an enzyme-based isotonic, cleaning solution and wetting agent formulated to clean the fluidic lines and baths.

2.5.5 Probe Cleanser

The probe cleanser is an alkaline cleaning solution formulated to clean the fluidic lines, apertures and baths.

2.5.6 Controls and Calibrators

The controls and calibrators are used to verify accurate operation of and calibrate the analyzer.

The controls are commercially prepared whole-blood products used to verify that the analyzer is functioning properly. They are available in low, normal, and high levels. Daily use of all levels verifies the operation of the analyzer and ensures reliable results are obtained. The calibrators are commercially prepared whole-blood products used to calibrate the analyzer.

Read and follow the instructions for use to use the controls and calibrators. All references related to controls and calibrators in this manual refer to the controls and calibrators reagents specifically formulated for this analyzer. You should buy those controls and calibrators from Mindrayor Mindray-authorized distributors.

3 Understanding the System Principles

3.1 Introduction

The two independent measurement methods used in this analyzer are:

- the Coulter method for determining the WBC, RBC, and PLT data;
- the colorimetric method for determining the HGB.

During each analysis cycle, the sample is aspirated, diluted and mixed before the determination for each parameter is performed.

3.2 Aspiration

This analyzer can process two types of blood samples – whole blood samples and prediluted blood samples.

If you are to analyze a whole blood sample, you can simply present the sample to the sample probe and press the aspirate key to aspirate 13μL of the sample into the analyzer.

If you are to analyze a capillary blood sample, you should first manually dilute the sample (20 μL of capillary sample needs to be diluted by 0.7mL of diluent) and then present the pre-diluted sample to the sample probe and press the aspirate key to aspirate 0.3ml of the sample into the analyzer.

3.3 Dilution

Usually in blood samples, the cells are too close to each other to be identified or counted. For this reason, the diluent is used to separate the cells so that they are drawn through the aperture one at a time as well as to create a conductive environment for cell counting. Moreover, red blood cells usually outnumber white blood cells by 1,000 times. For this reason, lyse needs to be added to the sample to eliminate the red cells before the WBC counting.

When analyzing a whole blood sample, this analyzer aspirates 13μL of the sample and follows the procedure presented in Figure3-1 to dilute it before proceeding to the actual analysis.

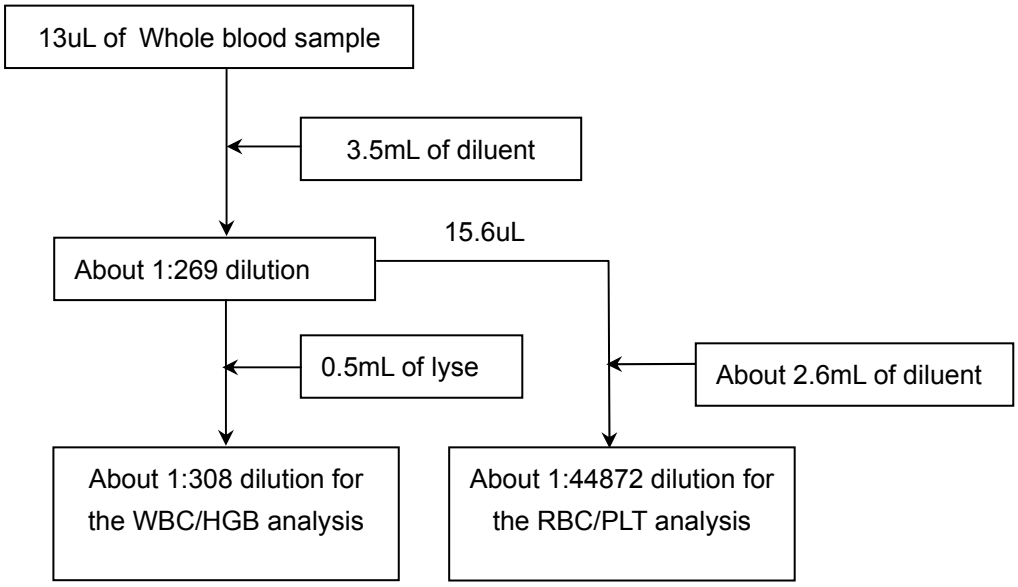

13uL of Whole blood sample
3.5mL of diluent
15.6uL
About 1:269 dilution
0.5mL of lyse
About 2.6mL of diluent
About 1:308 dilution for the WBC/HGB analysis
About 1:44872 dilution for the RBC/PLT analysis

Figure3-1 How a whole blood sample is diluted

When analyzing a prediluted sample, you should first collect 20μL of capillary sample and dispense 0.7mL of diluent from this analyzer to predilute it. Then the analyzer aspirates 0.3ml of the pre-diluted sample for further dilution, as Figure3-2 shows.

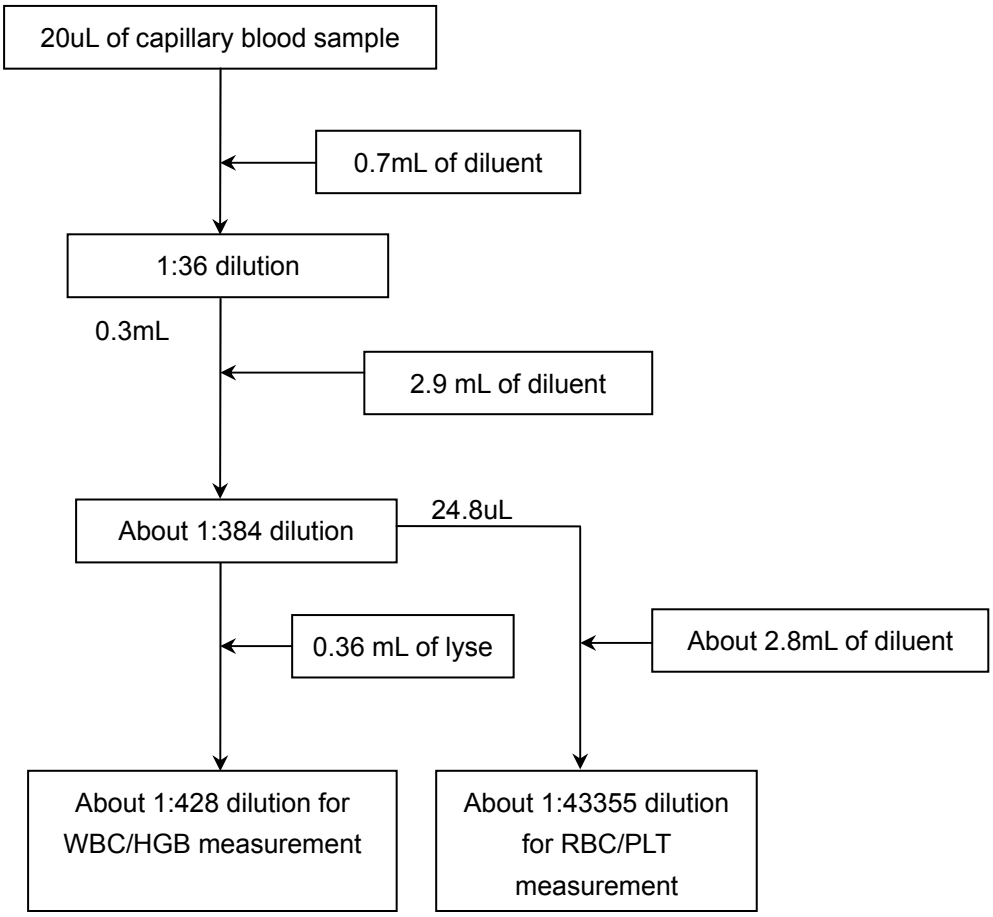


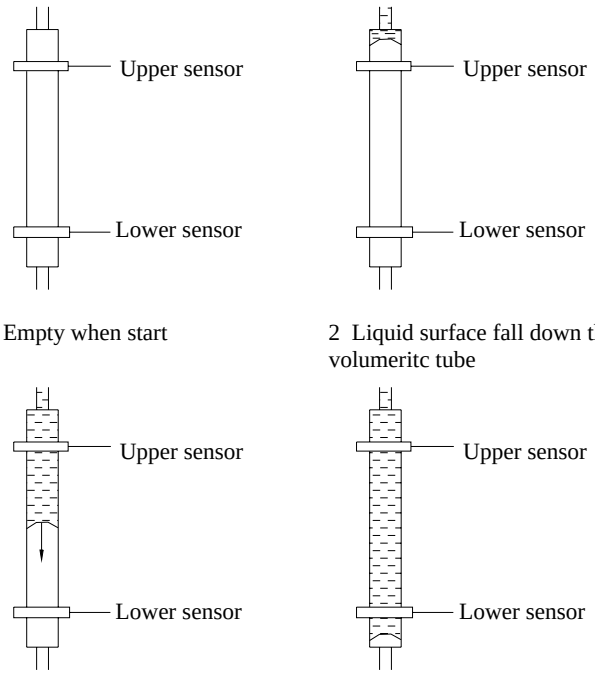
Figure3-2 How a capillary sample is diluted

3.4 WBC/HGB Measurement

3.4.1 Volumetric Metering

An accurate cell count cannot be obtained unless the precise volume of diluted sample that passes through the aperture during the count portion of the analysis cycle (the count cycle) is known. This analyzer uses a volumetric metering unit to control the count cycle and to ensure that a precise volume of sample is analyzed.

The metering unit controlling the WBC count cycle consists of a metering tube with two optical sensors mounted on it. This tube ensures that a precise amount of diluted sample is measured during each count cycle. The exact amount is determined by the distance between the two optical sensors. The rinse is used to create a meniscus in the metering tube. The count cycle starts when the meniscus reaches the upper sensor and stops when the meniscus reaches the lower sensor. The amount of time required for the meniscus to travel from the upper sensor to the lower sensor is called the WBC Count Time and is measured in seconds. At the end of the count cycle, the measured count time is compared to the pre-defined reference count time (see **Chapter 5.3** for details). If the former is less than or greater than the latter by 2 seconds or more, the analyzer will report a WBC bubble or WBC Clog error. Seeing the error message, you can refer to **Chapter 11 Troubleshooting Your Analyzer** for solutions.



1 Empty when start

2 Liquid surface fall down through the volumeritc tube

3 Counting start when the liquid surface pass the upper sensor.

4 Counting end when the liquid surface pass the lower sensor

Figure3-3 Volumetric metering process

3.4.2 Measurement Principles

- WBC measurement

WBCs are counted and sized by the Coulter method. This method is based on the measurement of changes in electrical resistance produced by a particle, which in this case is a blood cell, suspended in a conductive diluent as it passes through an aperture of known dimensions. An electrode is submerged in the liquid on both sides of the aperture to create an electrical pathway. As each particle passes through the aperture, a transitory change in the resistance between the electrodes is produced. This change produces a measurable electrical pulse. The number of pulses generated signals the number of particles that passed through the aperture. The amplitude of each pulse is proportional to the volume of each particle. Each pulse is amplified and compared to the internal reference voltage channels, which only accepts the pulses of a certain amplitude. If the pulse generated is above the WBC threshold, it is counted as a WBC.

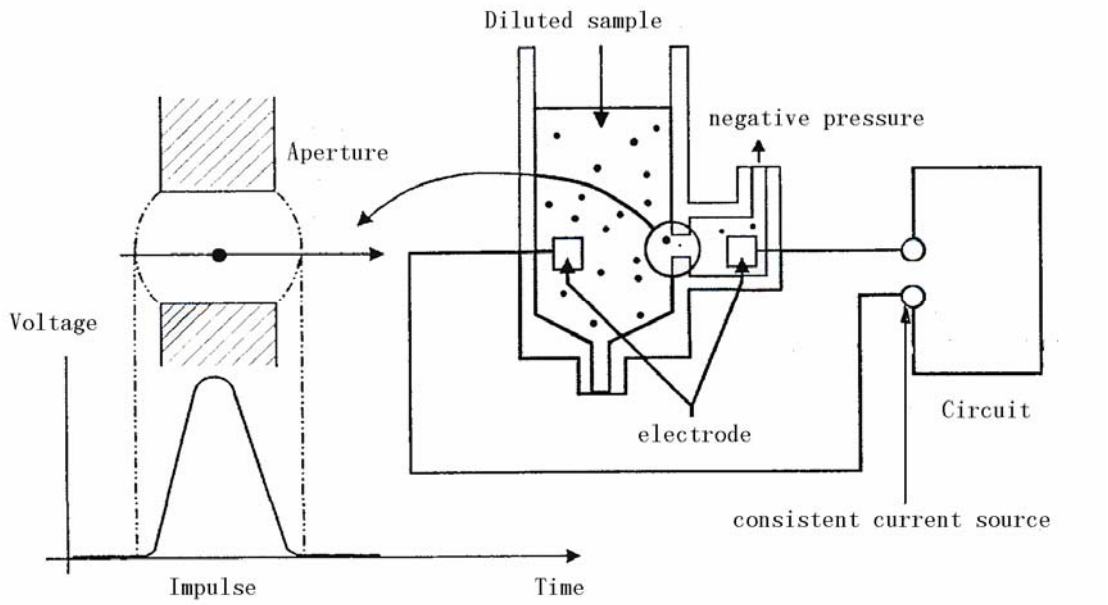


Figure3-4

- HGB measurement

HGB is determined by the colorimetric method. The WBC/HGB dilution is delivered to the WBC bath where it is bubble mixed with a certain amount of lyse, which converts hemoglobin to a hemoglobin complex that is measurable at 525 nm. An LED is mounted on one side of the bath and emits a beam of light, which passes through the sample and a 525nm filter, and then is measured by a photo-sensor that is mounted on the opposite side. The signal is then amplified and the voltage is measured and compared to the blank reference reading

(readings taken when there is only diluent in the bath). The HGB is calculated per the following equation and expressed in g/L.

$$HGB(g/L) = Constant \times Log_{10}(\text{Blank Photocurrent/Sample Photocurrent})$$

3.4.3 Derivation of WBC-Related Parameters

- WBC

WBC (10^9/ L) is the number of leukocytes measured directly by counting the white blood cells passing through the aperture. Note that when you observe NRBCs (nucleated red blood cells), which do not react with the lyse and can be mistaken by the analyzer for white cells, in the microscope, be sure to correct the system-generated result by the following formula,

$$WBC' = WBC \times \frac{100}{100 + NRBC}$$

where WBC represents the system-generated white cell number, NRBC the number of NRBCs counted in 100 white cells and WBC′ the corrected white cell number.

- WBC differentia

With the help of the diluent and lyse, this analyzer can size the white cells into three sub-populations - lymphocytes, mid-sized cells (including monocytes, basophils and eosinophils) and granulocytes. Based on the WBC histogram, this analyzer calculates Lymph%, Mid% and Gran% as follows and express the results in percents.

$$Lymph\% = \frac{PL}{PL + PM + PG} \times 100$$

$$Mid\% = \frac{PM}{PL + PM + PG} \times 100$$

$$Gran\% = \frac{PG}{PL + PM + PG} \times 100$$

where PLT = particles in the lymphocyte region ($10^9 / L$)

PM = particles in the mid size region ($10^9 / L$)

PG = particles in the granulocyte region ($10^9 / L$).

Having achieved the three parameters above, this analyzer proceeds to calculate the Lymph# , Mid# and Gran# per the following equations and express them in $10^9 / L$.

$$\text{Lymph\#} = \frac{\text{Lymph\%} \times \text{WBC}}{100}$$

$$\text{Mid\#} = \frac{\text{Mid\%} \times \text{WBC}}{100}$$

$$\text{Gran\#} = \frac{\text{Gran\%} \times \text{WBC}}{100}$$

- WBC histogram

Besides the parameters mentioned above, this analyzer also presents a WBC histogram, whose x-coordinate represents the cell volume（fL）and y-coordinate represents the number of the cells. The histogram is presented in the Analysis area of the "**Count**" screen when the analysis is done. You can also review the histograms of the stored patient results (see **Chapter 7 Reviewing Sample Results**).

The first three discriminators of the WBC histogram can be adjusted in case you are not satisfied with the result. Note that you cannot adjust them if the WBC result is less than 0.5 or out of the operating range.

3.4.4 HGB

Using the colorimetric method, this analyzer calculates hemoglobin concentration (g/L) as follows.

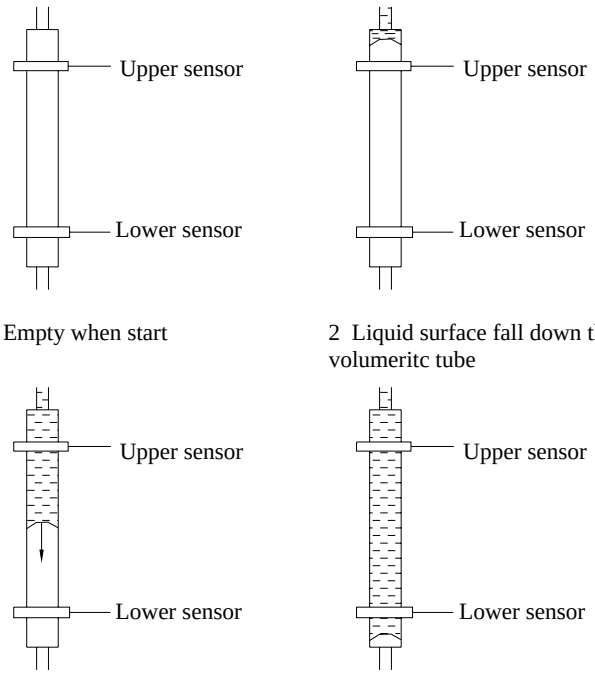
HGB(g/L)=Constant×Log_{10}(Blank Photocurrent/Sample Photocurrent)

3.5 RBC/PLT Measurement

3.5.1 Volumetric Metering

An accurate cell count cannot be obtained unless the precise volume of diluted sample that passes through the aperture during the count cycle is known. This analyzer uses a volumetric metering unit to control the count cycle and to ensure that a precise volume of sample is analyzed for the measurement.

The metering unit controlling the RBC/PLT count cycle consists of a metering tube with two optical sensors mounted on it. This tube ensures that a precise amount of diluted sample is measured during each count cycle. The exact amount is determined by the distance between the two optical sensors. The rinse is used to create a meniscus in the metering tube. The count cycle starts when the meniscus reaches the upper sensor and stops when the meniscus reaches the lower sensor. The amount of time required for the meniscus to travel from the upper sensor to the lower sensor is called the RBC Count Time and is measured in seconds. At the end of the count cycle, the measured count time is compared to the pre-defined reference count time (see **Chapter 5.3** for details). If the former is less than or greater than the latter by 2 seconds or more, the analyzer will report a RBC bubble or RBC Clog error. Seeing the error message, refer to **Chapter 11 Troubleshooting** for solutions.



1 Empty when start

2 Liquid surface fall down through the volumeritc tube

3 Counting start when the liquid surface pass the upper sensor.

4 Counting end when the liquid surface pass the lower sensor

Figure3-5 Volumetric metering process

3.5.2 Measurement Principles

- RBC/PLT measurement

RBCs/PLTs are counted and sized by the Coulter method. This method is based on the measurement of changes in electrical resistance produced by a particle, which in this case is a blood cell, suspended in a conductive diluent as it passes through an aperture of known dimensions. An electrode is submerged in the liquid on both sides of the aperture to create an electrical pathway. As each particle passes through the aperture, a transitory change in the resistance between the electrodes is produced. This change produces a measurable electrical pulse. The number of pulses generated signals the number of particles that passed through the aperture. The amplitude of each pulse is proportional to the volume of each particle. Each pulse is amplified and compared to the internal reference voltage channels, which only accepts the pulses of a certain amplitude. If the pulse generated is above the RBC/PLT lower threshold, it is counted as a RBC/PLT.

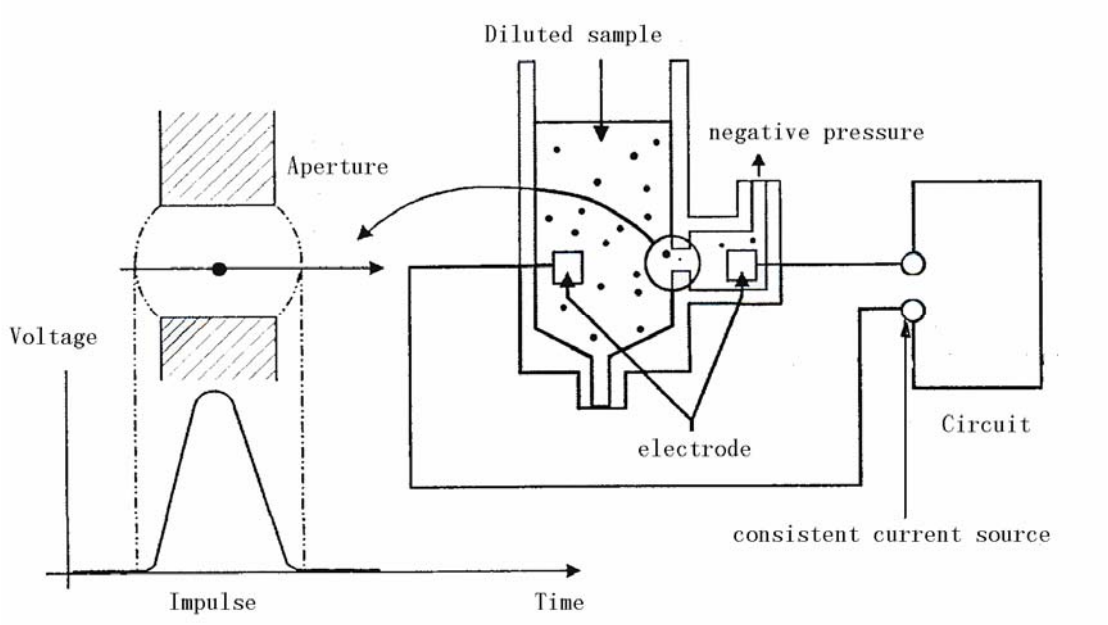


Figure3-6

3.5.3 Derivation of RBC-Related Parameters

- RBC

RBC (10^{12}/L) is the number of erythrocytes measured directly by counting the erythrocytes passing through the aperture.

- MCV

Based on the RBC histogram, this analyzer calculates the mean cell volume (MCV) and expresses the result in fL .

This analyzer calculates the HCT (%), MCH (pg) and MCHC (g/L) as follows:

This analyzer calculates the HCT (%), MCH (pg) and MCHC(g/L) as follows:

$$HCT = \frac{RBC \times MCV}{10}$$

$$MCH = \frac{HGB}{RBC}$$

$$MCHC = \frac{HGB}{HCT} \times 100$$

Where the RBC is expressed in 10^{12}/L，MCV in fL and HGB in g/L.

- RDW-CV

Based on the RBC histogram, this analyzer calculates the CV (Coefficient of Variation) of the erythrocyte distribution width.

- RDW-SD

RDW-SD (RBC Distribution Width – Standard Deviation, fL) is set on the 20% frequency level with the peak taken as 100%, Figure3-7 shows.

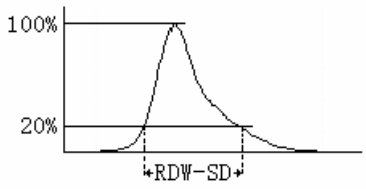


Figure3-7

- RBC Histogram

Besides the parameters mentioned above, this analyzer also presents a RBC histogram, whose x-coordinate represents the cell volume（fL）and y-coordinate represents the number of the cells. The histogram is presented in the Analysis area of the "**Count**" screen when the analysis is done. You can also review the histograms of the stored patient results (see **Chapter 7 Reviewing Sample Results**).

The two discriminators of the RBC histogram can be adjusted in case you are not satisfied with the result. Note that you cannot adjust them if the RBC result is less than 0.2 or out of the operating range.

3.5.4 Derivation of PLT-Related Parameters

- PLT

PLT (10^9/L) is measured directly by counting the platelets passing through the aperture.。

- MPV

Based on the PLT histogram, this analyzer calculates the mean platelet volume (MPV, fL).

- PDW

Platelet distribution width (PDW) is the geometric standard deviation (GSD) of the platelet size distribution. Each PDW result is derived from the platelet histogram data and is reported as 10(GSD).

- PCT

This analyzer calculates the PCT as follows and express it in ％.
Where the PLT is expressed in 10^9/L and the MPV in fL.

$$\mathrm{PCT} = \frac{\mathrm{PLT} \times \mathrm{MPV}}{10000}$$

- PLT Histogram

Besides the parameters mentioned above, this analyzer also presents a PLT histogram, whose x-coordinate represents the cell volume（fL）and y-coordinate represents the number of the cells. The histogram is presented in the Analysis area of the "**Count**" screen when the analysis is done. You can also review the histograms of the stored patient results (see **Chapter 7 Reviewing Sample Results**).

The two discriminators of the PLT histogram can be adjusted in case you are not satisfied with the result. Note that you cannot adjust them if the PLT result is less than 10 or out of the operating range.

3.6 Wash

After each analysis cycle, each element of the analyzer is washed.

- The sample probe is washed internally and externally with diluent;
- The WBC bath is washed with diluent and rinse;
- The RBC/PLT bath is washed with diluent and rinse;
- The metering tube is washed with rinse.

4 Installing Your Analyzer

4.1 Introduction

This chapter introduces the installation procedure of the BC-3000 Plus. To ensure all system components are functioning correctly and to verify system performance, a Mindray-authorized representative will handle the installation and initial software setup.

⚠ CAUTION

- **Installation by personnel not authorized or trained by Mindray may damage your analyzer. Do not install your analyzer without the presence of Mindray -authorized personnel.**

4.2 Installation Requirements

Before installation, you should ensure that the following space, power and environmental requirements are met.

4.2.1 Space Requirements

Check the site for proper space allocation. In addition to the space required for the analyzer itself, arrange for

- at least 28 cm on each side, which is the preferred access to perform service procedures;
- at least 10 cm behind for cabling and ventilation;
- enough room on or below the countertop to accommodate the diluent, rinse and waste containers.

4.2.2 Power Requirements

Check the availability of a power outlet that is

- a female receptacle;
- single phase with ground (confirmed third-wire earth ground);
- 100 VAC - 240 VAC;
- 50/60 Hz.

⚠ WARNING

- **Make sure the analyzer is properly grounded.**
- **If a power outlet with confirmed third-wire earth ground is not available, be sure to connect the equipotentiality pole at the back of the analyzer to the ground.**
- **Only install a 250V T4A fuse on the analyzer.**
- **Before turning on the analyzer, make sure the input voltage meets the above requirements.**

4.2.3 General Environment

- Operating temperature: 15 ℃ - 35 ℃;
- Optimal operating temperature: 15 ℃ - 30 ℃;

NOTE

- **The specified temperature range is necessary to obtain reliable analysis results.**

- Relative humidity: 30% -85%;
- Atmospheric pressure: 70 kPa -106 kPa;
- The environment should be as free as possible from dust, mechanical vibrations, loud noises, and electrical interference;
- Do not place the analyzer near brush-type motors, flickering fluorescent lights, and electrical contacts that regularly open and close;
- Do not place the analyzer in direct sunlight or in front of a source of heat or drafts.

⚠ WARNING

- **Do not place the analyzer in a flammable or explosive environment.**

4.3 Unpacking

4.3.1 Unpacking and Inspecting the Analyzer

Your analyzer is tested before it is shipped from the factory. International symbols and special handling instructions tell the carrier how to treat this electronic instrument. When you receive your analyzer, carefully inspect the carton. If you see any signs of mishandling or damage, contact Mindray customer service department or your local distributor immediately. When you are sure the carton is fine, follow the steps below to unpack the analyzer:

1. Place the carton on the floor upright with the arrows on the side upwards;
2. Remove the tape and take out the accessory box. Check the accessories against the packing list. Notify the Mindray customer service department or your local distributor immediately if you find anything missing;
3. Open the main box and check the items inside against the packing list. Notify the Mindray customer service department or your local distributor immediately if you find anything missing;
4. Remove the top protective foam. Firmly grip the two cardboard handles and lift the analyzer out of the box and place it on the floor. Carry the analyzer away from the foam and set it on the countertop.

NOTE

- **Be sure to retain the shipping carton and all the packing materials, as they can be used for packaging if analyzer must be reshipped.**

4.3.2 How to move the analyzer

■ If the carton is intact, you may use a plate and fork-lifter to move the analyzer for a short distance;

■ If your analyzer has been used for a while, do the"**Empty Tubing**" procedure and shut it down before moving it;

⚠ WARNING

- **Never move the analyzer without draining the fluidic lines.**

■ For a short - distance moving on a smooth ground, you may use a trolley to facilitate the transportation;

■ During the moving process, be sure to protect the LCD and the sample probe from excessive force and from contact with other objects;

■ Be sure to keep the analyzer upright during the moving process. Do not tilt or incline it;

■ Do your best to minimize the mechanical shock when moving the analyzer. After a long-distance moving, check and tune the analyzer before using it.

4.4 Installation Procedure

4.4.1 Releasing sample probe

⚠ WARNING

- **The sample probe tip is sharp and may contain biohazardous materials. Exercise caution to avoid contact with the probe when working around it.**

Before the analyzer is shipped out, the sample probe is fixed by a plastic cable tie to avoid damage during shipment. After unpacking the analyzers, you need to release the sample probe as follows:

1. Push the right door latch in the direction indicated in Figure 4-1 to open the right door;

Figure 4-1

2. Lift up the front panel latch as indicated in Figure 4-2 and open the front panel;

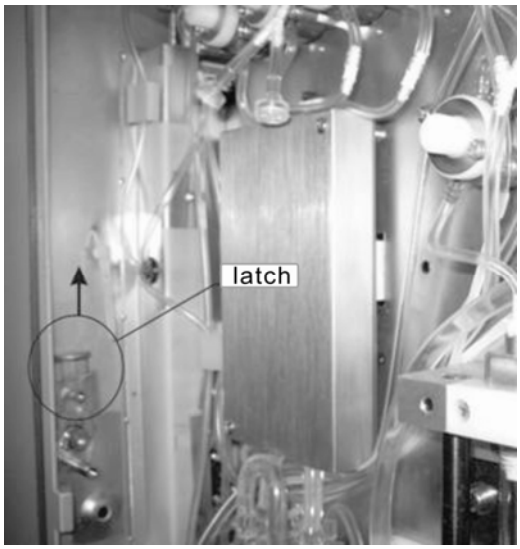


Figure 4-2

3. Cut the plastic cable tie to release the probe, as Figure 4-3 shows;

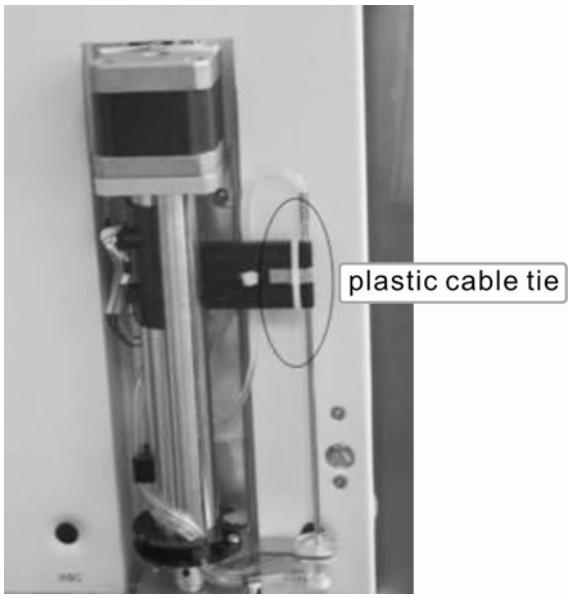


Figure 4-3

4. The released sample probe is shown in Figure 4-4;

Figure 4-4

5. Lift the front panel latch and close the front panel and then release the latch to lock it. Finally close the right door.

4.4.2 Connecting Reagent Containers

- **Consider all materials (samples, reagents, controls, calibrators, or components that contain or have contacted human blood) as being potentially infectious. Wear proper laboratory attire (including rubber gloves, a laboratory coat, and eye protection) and follow safe laboratory procedures when handling any material in the laboratory.**
- **If the reagents accidentally spill on your skin, wash them off with plenty of water and if necessary, go see a doctor; if the reagents accidentally spill into your eyes, wash them off with plenty of water and immediately go see a doctor.**

NOTE

- **Be sure to use the manufacturer-specified reagents.**
- **Be sure to keep the reagents still for a while before using them.**
- **Be sure not to use expired reagents.**
- **To prevent contamination, be sure to tighten the container caps when the installation is finished.**

■ Connecting the lyse container

1. Push the left door latch in the direction indicated in Figure 4-5 to open the left door;

Figure 4-5

2. Locate the black and orange fittings as shown in Figure 4-6;

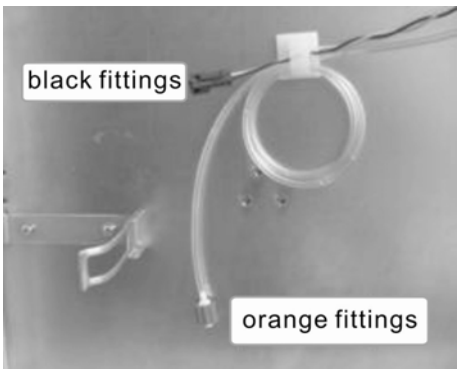


Figure 4-6

3. Take out the lyse pickup tube with an orange connector (see Figure4-7) from the accessory box. Take out the lyse container, in which there should be enough lyse. Remove the container cap and insert the double-pronged end of the tube into the container and turn (clockwise) the tube's cap onto the lyse container until properly secured;

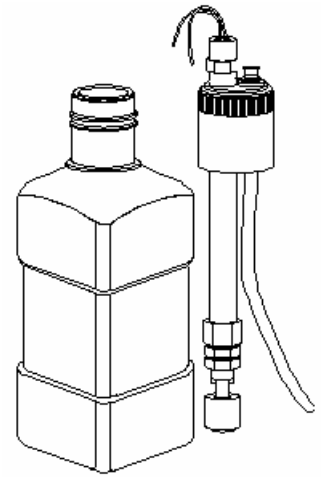


Figure 4-7

4. Place the lyse container onto the shelf and connect the black connector on the cap to the black fitting and the orange connector to the orange fitting, as Figure 4-8 shows.

Figure4-8

■ Connecting diluent container

1. Take out the diluent pickup tube with a green connector (Figure 4-9) from the accessory box;
2. Take out the diluent container, in which there should be enough diluent, and place it on or below the countertop;
3. Remove the container cap and insert the double-pronged end of the tube into the diluent container and turn the tube's cap onto the diluent container until properly secured;

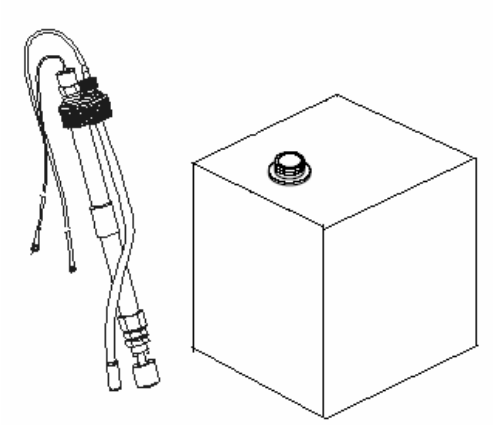


Figure4-9

4. Locate the green fitting, marked DILUENT, in the lower right corner of the back of the analyzer. Plug the green connector of the tube into the fitting and turn it clockwise until properly secured;
5. Locate the transducer fitting, marked DILUENT, in the lower right corner of the back of the analyzer. Connect the wire by pushing in and turning until properly secured.

■ Connecting rinse container

1. Take out the diluent pickup tube with a blue connector (see Figure 4-10) from the accessory box;
2. Take out the rinse container, in which there should be enough diluent, and place it on or below the countertop;
3. Remove the container cap and insert the double-pronged end of the tube into the rinse container and turn clockwise the tube's cap onto the diluent container until properly secured;

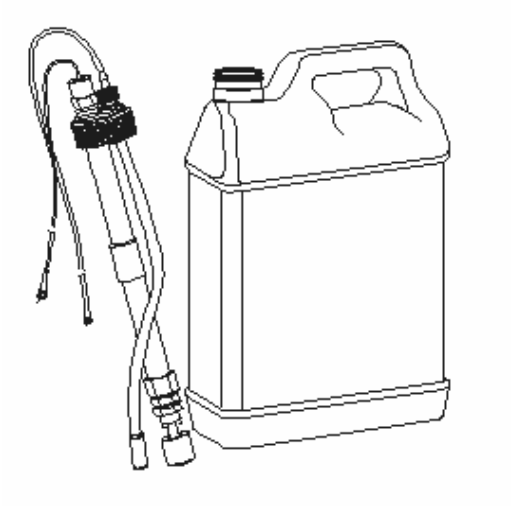


Figure 4-10

4. Locate the green fitting, marked RINSE, in the lower right corner of the back of the analyzer. Plug the blue connector of the tube into the fitting and turn it clockwise until properly secured;
5. Locate the transducer fitting, marked RINSE, in the lower right corner of the back of the analyzer. Connect the wire by pushing in and turning until properly secured.

■ Connect waste container

1. Take out the waste tube with a red connector from the accessory box;
2. Locate the red fitting, marked WASTE, in the lower right corner of the back of the analyzer. Plug the red connector of the tube into the fitting and turn it clockwise until properly secured;
3. Prepare a container to receive the waste and place it on or below the countertop;
4. Insert the waste tube into the waste container.

4.4.3 Installing Recorder Paper

Follow the procedure below to install the recorder paper.

⚠ CAUTION

- **Improper installation of recorder paper may jam the paper and/or result in blank printouts.**

1. Locate the projecting part in the upper right corner of the recorder and press it in the direction shown in Figure 4-11 to open it;

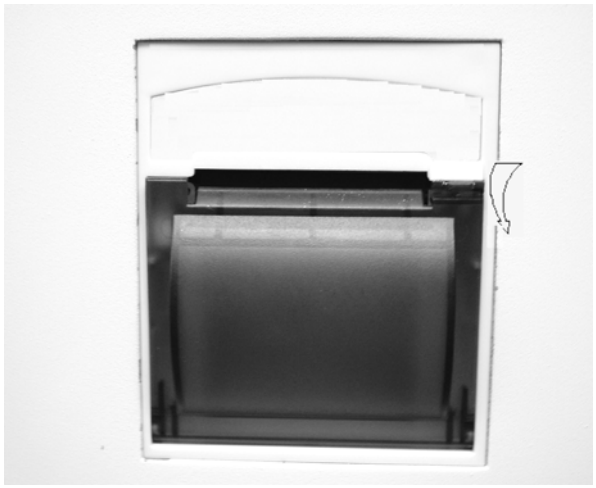


Figure 4-11

2. Flip the paper tension lever on the left side upwards. Keep the printing side face-down. Insert the pointed end of the paper into the slot below the paper rod and push the paper until it comes out from above the rod. Pull the paper out. Keep the paper centered and place the paper into the paper holder. See Figure 4-12;

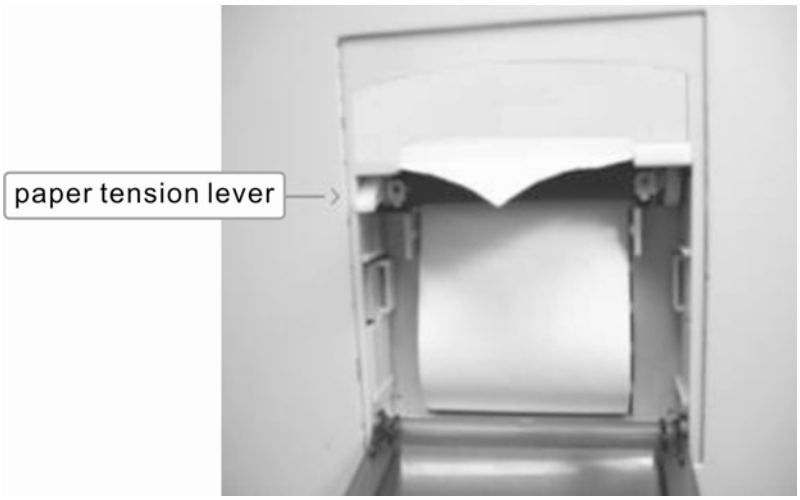


Figure 4-12

NOTE

- **The recorder paper is treated on one side for printing. To determine which side is the printing side, gently scratch both sides with nails and the one with visible nail trace left is the printing side.**

3. Flip the paper tension level downwards to lock the paper in place, as Figure 4-13 shows.

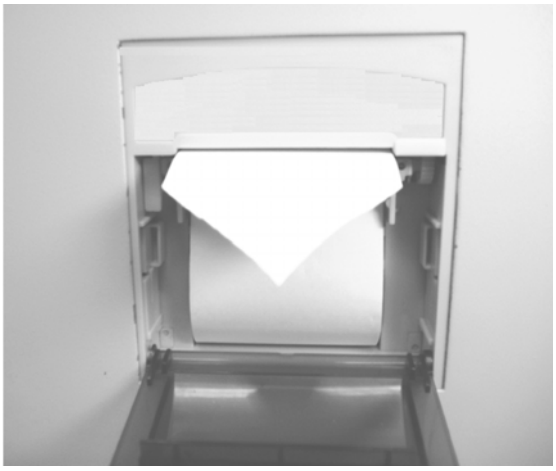


Figure 4-13

4. Close the recorder door, as Figure 4-14 shows;

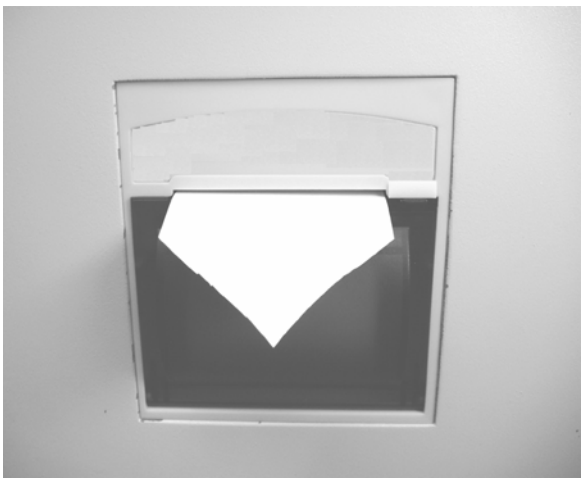


Figure 4-14

4.4.4 Connecting the Keyboard

Take out the keyboard from the accessory kit and connect it to the keyboard interface marked “KB” at the back of the analyzer.

4.4.5 Connecting the Printer (Optional)

Follow the printer’s instructions for use to connect the printer to the parallel port at the back of the analyzer.

4.4.6 Connecting the Bar-Code Scanner (Optional)

Follow the scanner’s instructions for use to connect the scanner to the serial port1 at the back of the analyzer.

NOTE

- **Be sure to use the printer and/or scanner of the specified model.**

4.5 Starting the Analyzer

Take out the power cord from the accessory box. Plug the non-pronged end into the AC input at the back of the analyzer and the pronged end into an electrical outlet. Place the power switch at the back of the analyzer in the ON position (1) to turn on the analyzer. The power indicator light will be illuminated and the screen will display "**Initializing…**"**.** The analyzer will sequentially initialize the file, hardware and fluidic systems and the whole initializing process lasts about 3 - 4 minutes. When the initialization is finished, the analyzer will automatically enter the "**Count**" screen.

5 Customizing the Analyzer Software

5.1 Introduction

The BC-3000 Plus is a flexible laboratory instrument that can be tailed to your work environment. You can use the "**Setup**"program to customize the software options as introduced in chapters 5.2 - 5.13.

5.2 Print

The "**Print**" screen is where you set printing options.

5.2.1 Entering the "Print" screen

Press [MENU] to enter the system menu.

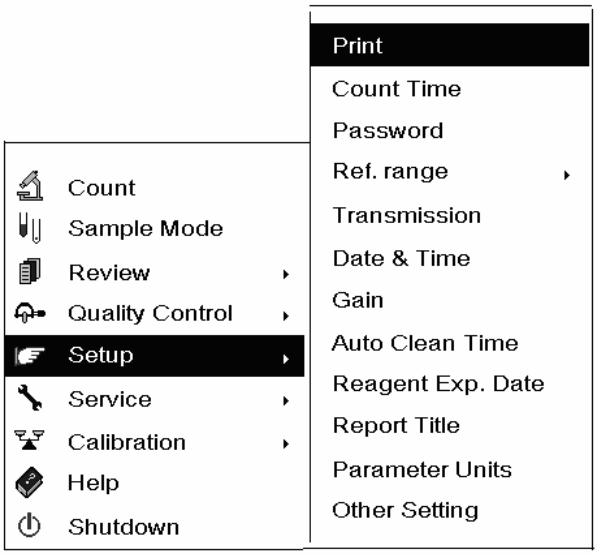


Figure 5-1System menu

SELECT "**Setup** → **Print**" (Figure 5-1) to enter the "**Print**" screen（Figure 5-2）.

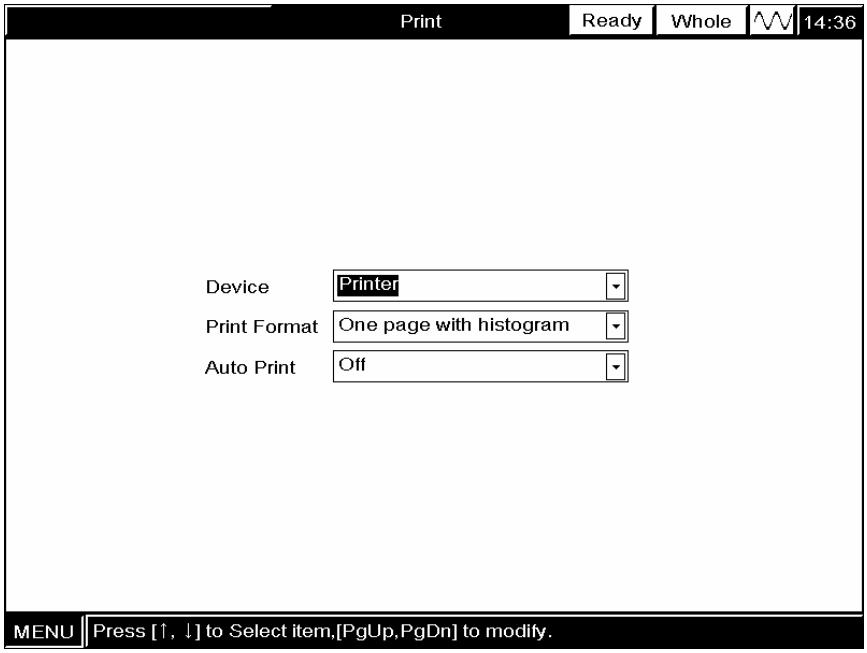


Figure 5-2 "Print" screen

5.2.2 Selecting printing device

You can select either the built-in recorder or an external printer (if available) as the printing device, as Figure 5-3 shows.

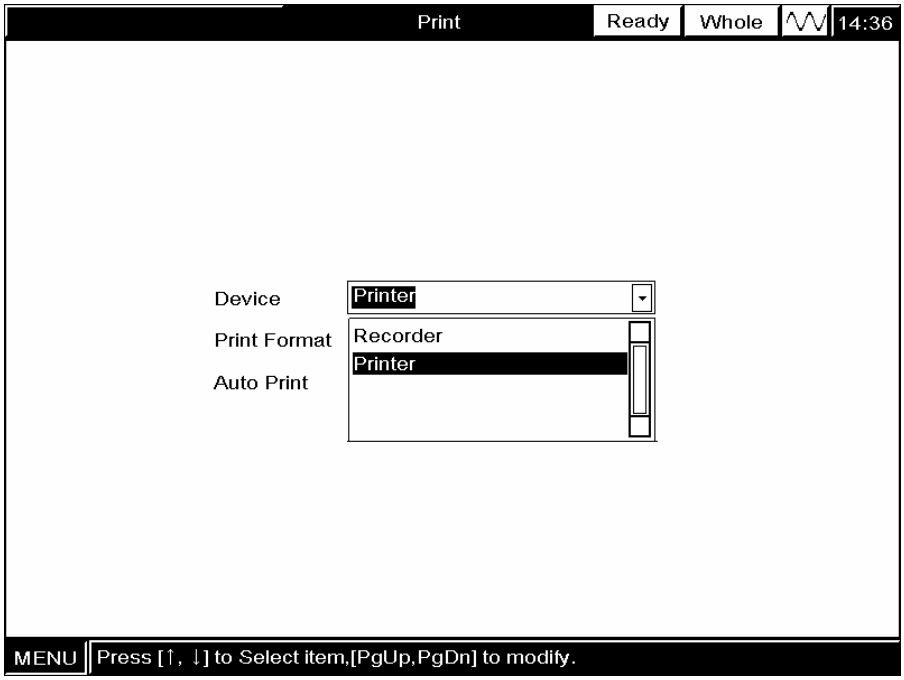


Figure 5-3 Selecting printing device

- If you prefer the recorder, ***SELECT*** "**Recorder**" ***from the*** "**Device**" ***pull-down list.***
- If you prefer the printer, ***SELECT*** "**Printer**" ***from the*** "**Device**" ***pull-down list.***

5.2.3 Selecting printing format

If you have selected the printer, you can choose either of the following printing formats.

- One page with histogram;
- One page without histogram.

To choose the desired format, ***SELECT*** the desired format ***from the*** "**Print Format**" ***pull-down list***, as Figure 5-4 shows.

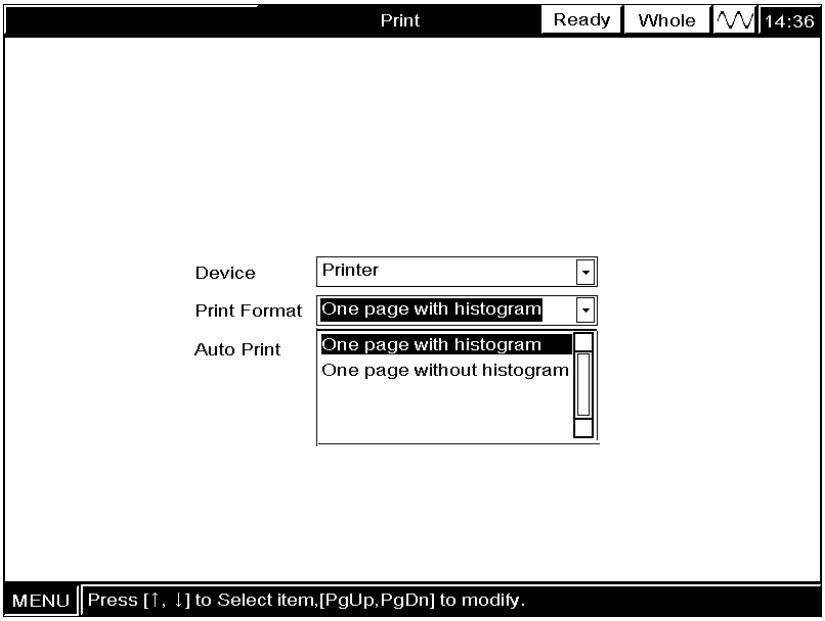


Figure 5-4 Selecting printing format for the printer

If you have selected the recorder, you can choose any of the following 4 printing formats.

- Format1 - parameter values + histograms;
- Format2 – parameter values only;
- Format3 - parameter values + histograms;
- Format4 - parameter values only.

To choose the desired format, ***SELECT*** the desired format ***from the*** "**Print Format**" ***pull-down list***, as Figure 5-5 shows.

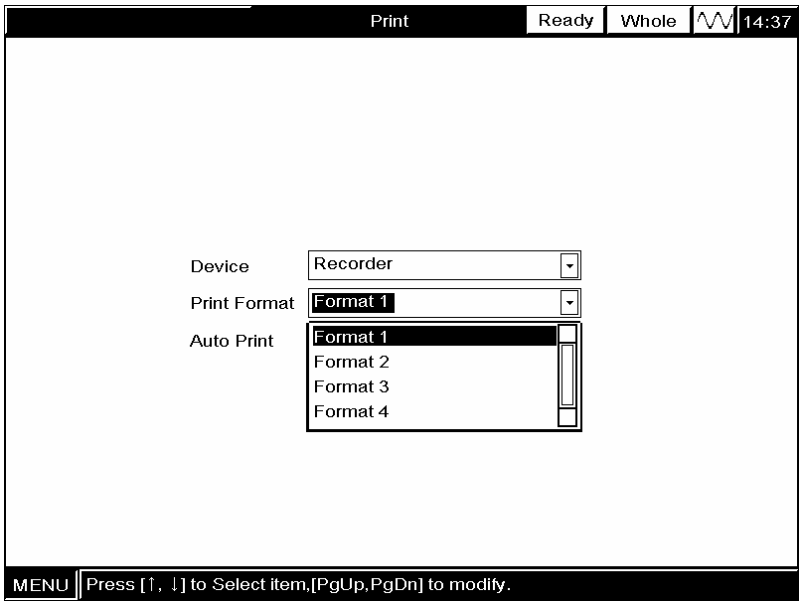


Figure 5-5 Selecting printing format for the recorder

5.2.4 Enabling/disabling Auto print

If the "**Auto Print** " function is on, the analysis result will be automatically printed out once the analysis is finished. To enable (or disable) this function, ***SELECT*** "**ON**"(or "**OFF**") ***from the*** "**Auto Print**" ***pull-down list***, as Figure 5-6 shows.

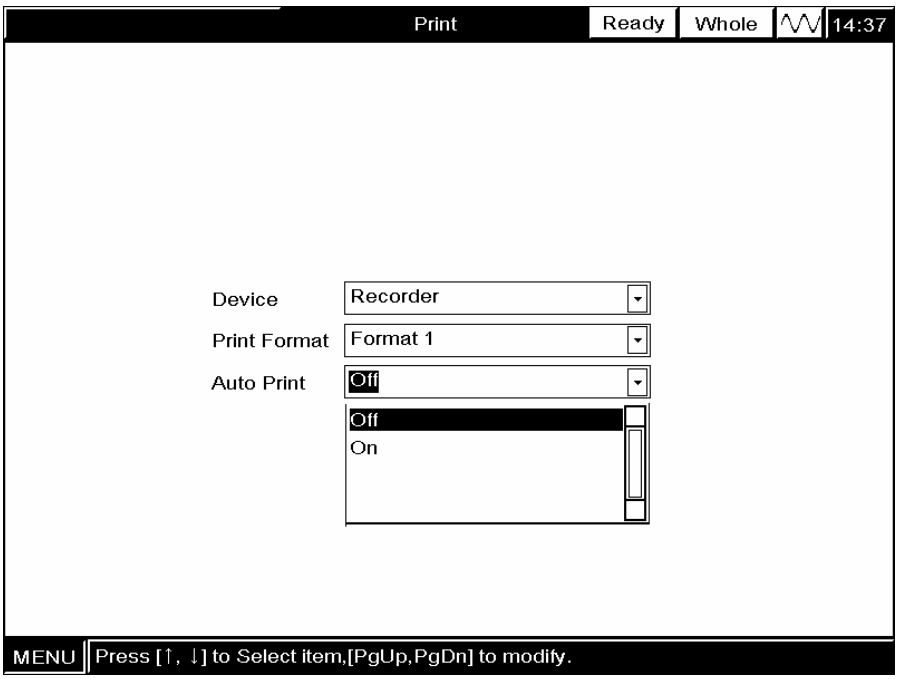


Figure 5-6 Enabling/disabling auto print

5.2.5 Exiting the "Print" screen

Press [MENU] to exit to the system menu or [MAIN] to exit to the "**Count**" screen, and the changes will be saved automatically.

5.3 Count time

The "**Count Time**" screen is where you view and/or set (if you have the administrator password) the reference time for the WBC and/or RBC count portion of the measurement cycle. If the actual WBC or RBC count time (see **Chapter 3.4.1 and 3.5.1**) deviates from the reference time by 2 seconds or more, the analyzer will alarm you for clogging or bubbles and invalidate the results of all related parameters.

5.3.1 Entering the "Count Time" screen and viewing the settings

Press [MENU] to enter the system menu.

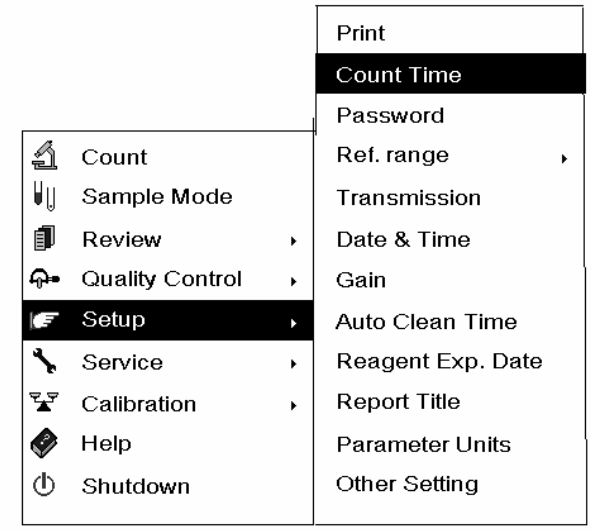


Figure 5-7 System menu

SELECT "**Setup → Count Time**"（Figure 5-7）to enter the "**Count Time**" screen (Figure 5-8)**.**

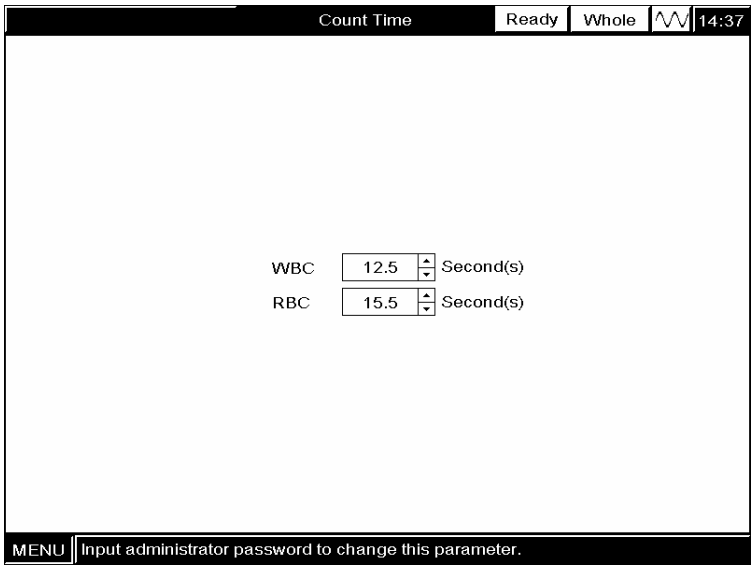


Figure 5-8 "Count Time" screen

5.3.2 Setting Count Time

1. Enter the administrator password as instructed by **Chapter 5.4.1**.
2. Enter the "**Count Time**" screen.
3. ***ENTER*** the desired number into the "**WBC Count Time**" box or "**RBC Count Time**" box to set the reference WBC or RBC count time.

5.3.3 Exiting "Count Time" screen

Press [MENU] to exit to the system menu or [MAIN] to exit to the "**Count**" screen, and the changes will be saved automatically.

5.4 Password

The BC-3000 Plus classifies users into two categories: common users (default) and administrators. You need to enter the administrator password to adjust certain options such as WBC/RBC Count Time, Gain, etc.

5.4.1 Entering the administrator password

Press [MENU] to enter the system menu.

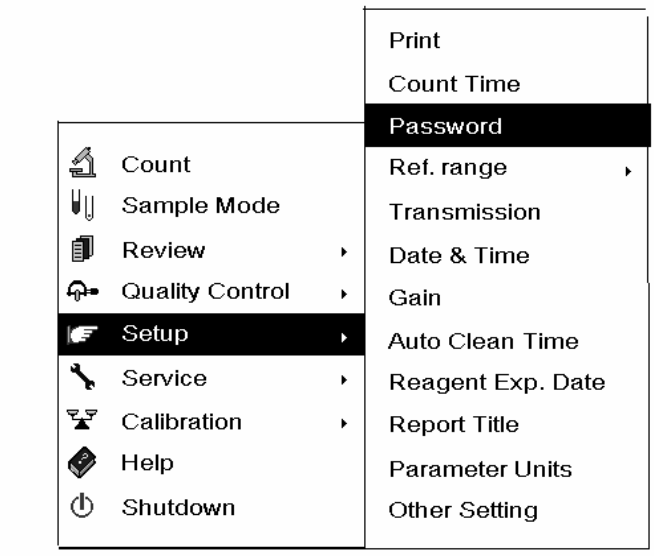


Figure 5-9 System menu

SELECT "**Setup → Password**" (Figure 5-9) to enter the "**Password**" screen (Figure 5-10).

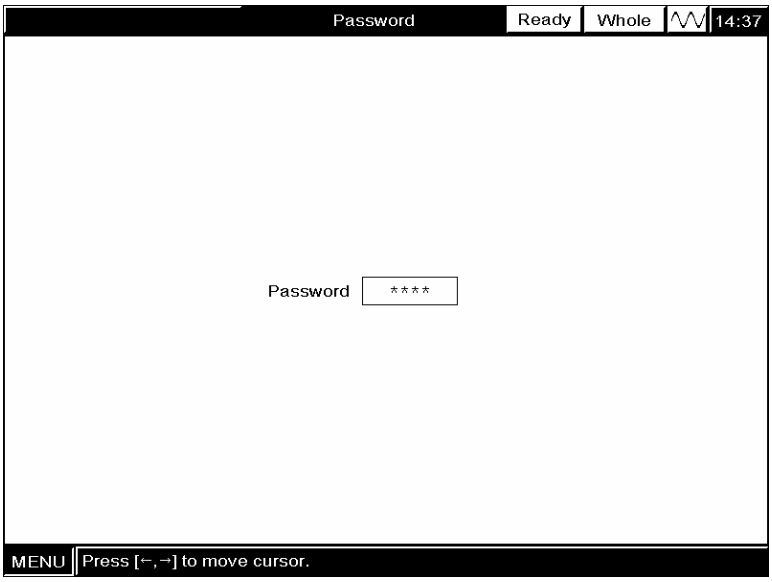


Figure 5-10 "Password" screen

ENTER "3000" and a message box will pop up to remind you of the current password level, as Figure 5-11 shows.

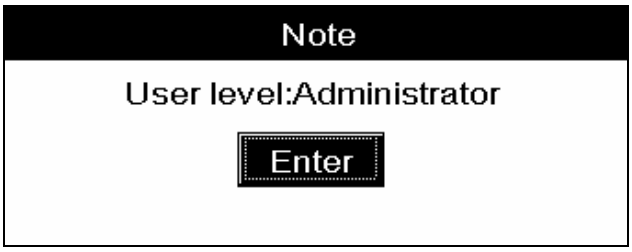


Figure 5-11 A message box to confirm the user level

CLICK "**Enter**" to confirm the password and exit to the system menu.

5.4.2 Resuming the common user password

Enter the "**Password**" screen and the default password is the common user password.

Press [MENU] again and a message box will pop up to remind you of the current password level, as Figure 5-12 shows.

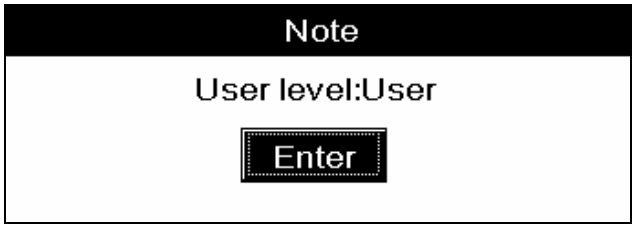


Figure 5-12 A message box to confirm the user level

CLICK "**Enter**" to confirm the password and exit to the system menu.

5.4.3 Ref. Range

The "**Ref. Range**" screen is where you view and/or set (if you have the administrator password) the high and low limits for your patients. The analyzer flags any parameter value above (H) or below (L) these limits.

This analyzer divides patients into 5 demographic groups, as Table 5-1shows.

Table 5-1 Demographic groups

Group	Gender	Age
General	Not specified, male or female.	Not specified.
	Not specified.	＞ 12 years
Man	Male	＞ 12 years
Woman	Female	＞ 12 years
Child	Male or Female	＞ 28 days and ≤12 years
Neonate	Male or Female	≤ 28 days

5.4.4 Viewing the limits (e.g. “General”)

Press [MENU] to enter the system menu.

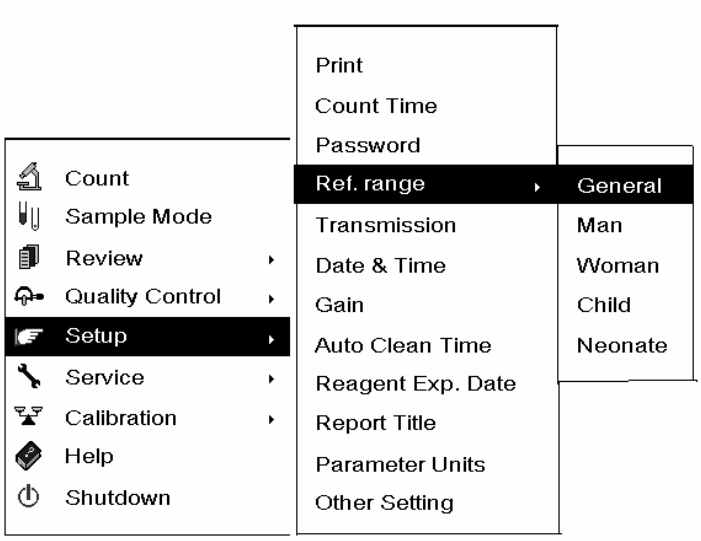
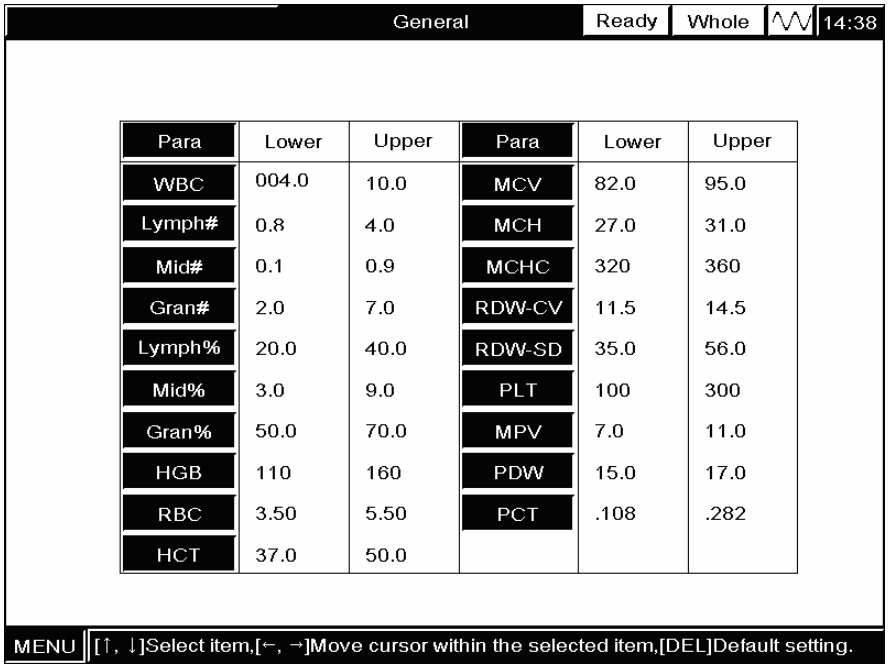


Figure 5-13 System menu

SELECT “**Setup→ Ref. Range→ General**”(Figure 5-13) to view the limits.



Para	Lower	Upper	Para	Lower	Upper
WBC	004.0	10.0	MCV	82.0	95.0
Lymph#	0.8	4.0	MCH	27.0	31.0
Mid#	0.1	0.9	MCHC	320	360
Gran#	2.0	7.0	RDW-CV	11.5	14.5
Lymph%	20.0	40.0	RDW-SD	35.0	56.0
Mid%	3.0	9.0	PLT	100	300
Gran%	50.0	70.0	MPV	7.0	11.0
HGB	110	160	PDW	15.0	17.0
RBC	3.50	5.50	PCT	.108	.282
HCT	37.0	50.0			

Figure 5-14 "General" screen

NOTE

- **Manufacturer-recommended ranges of all 19 parameters are available for the General, Man, Woman and Child groups. As for the Neonate group, manufacturer-recommended ranges are available for WBC, Lymph#, RBC, HGB and PLT only and the rest, if deemed necessary, can be set by the users themselves.**

5.4.5 Setting the limits (e.g. the "General" group)

1. Enter the administrator password as introduced in **Chapter 5*.4.1***;
2. Enter the "**General**" screen, as Figure 5-15 shows;
3. ***ENTER*** the new limits as desired;

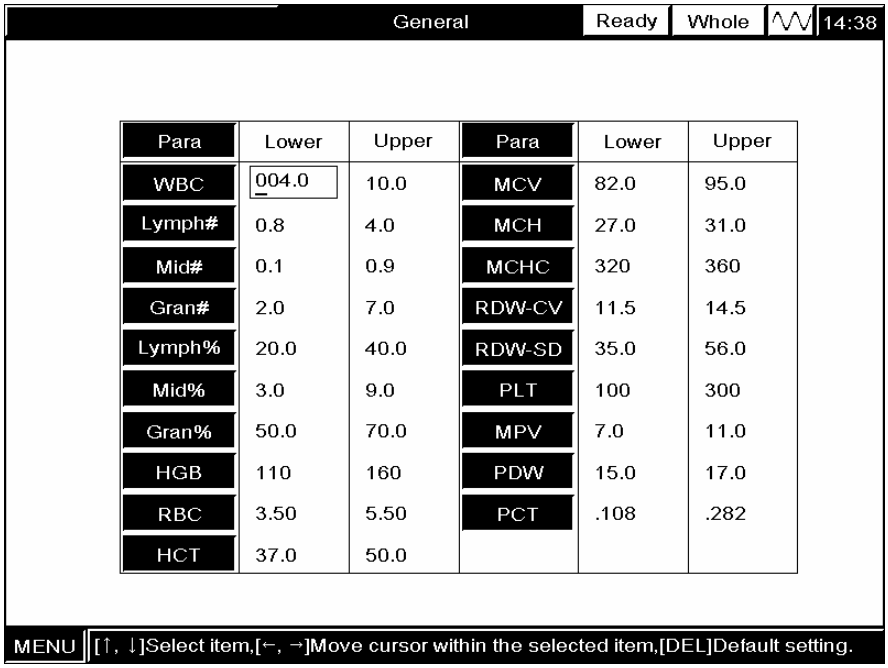


Figure 5-15 "General"screen

5.4.6 Exiting the "Ref.Range" screen (e.g. the "General" group)

Press [MENU] to exit to the system menu; press [MAIN] to return to the "**Count**" screen. If you have made any changes, a message box will pop up to ask you to save the changes, as Figure 5-16 shows. ***CLICK*** "**Enter**" to save the changes and exit to the system menu or the main screen; ***CLICK*** "**Cancel**" to abort the changes and exit to the system menu or the "**Count**" screen.

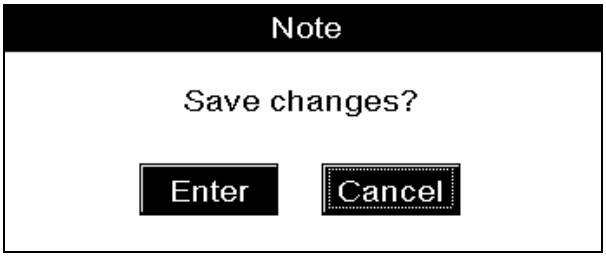


Figure 5-16 A message box to confirm the changes

NOTE

- **At the "General" screen (or the screen of any other group), you can press [PRINT] to print out the displayed limits.**
- **At the "General" screen (or the screen of any other group), you can press [DEL] to resume the manufacturer-recommended settings.**

5.5 Transmission

The "**Transmission**" screen is where you set communication parameters.

5.5.1 Entering the "Transmission" screen

Press [MENU] to enter the system menu.

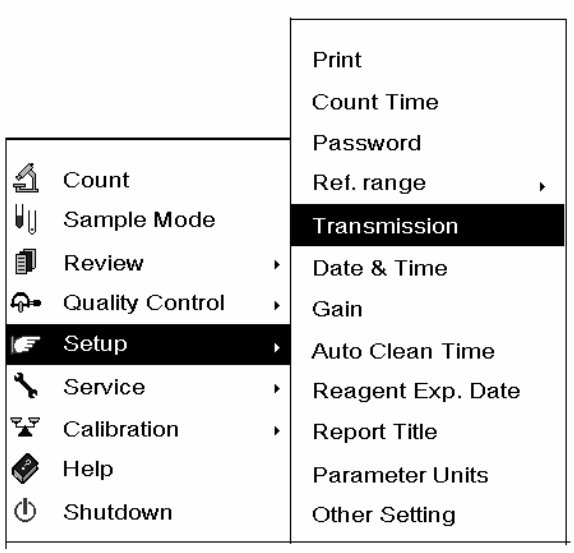


Figure 5-17 System menu

SELECT "**Setup→Transmission**" (Figure 5-17) to enter the "**Transmission**" screen (Figure 5-18)**.**

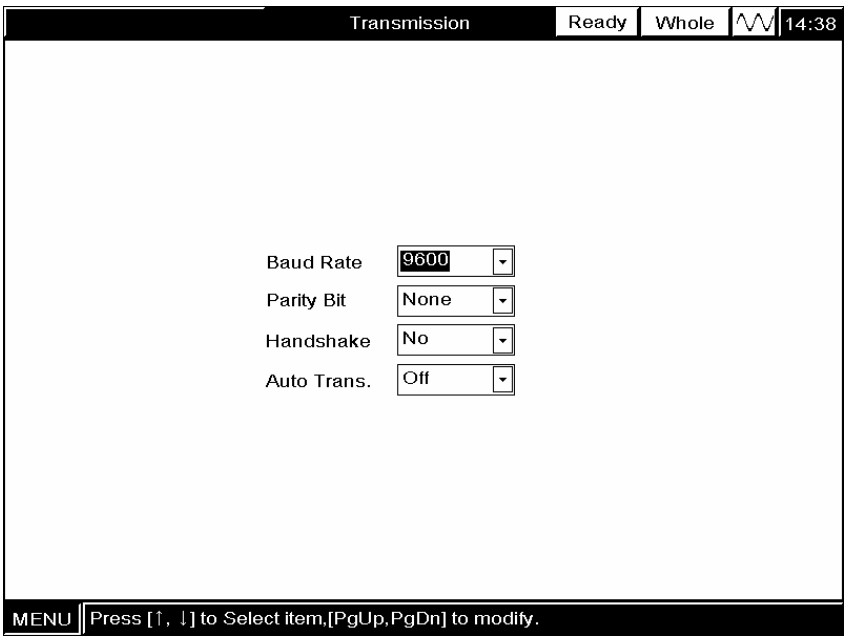


Figure 5-18 "Transmission" screen

5.5.2 Selecting baud rate

Five baud rate options are available: "**19200**", "**9600**"(default), "**4800**", "**2400**" and "**1200**". To select the desired baud rate, ***SELECT*** the desired rate ***from the*** "**Baud Rate**"***pull-down list***, as Figure 5-19 shows***.***

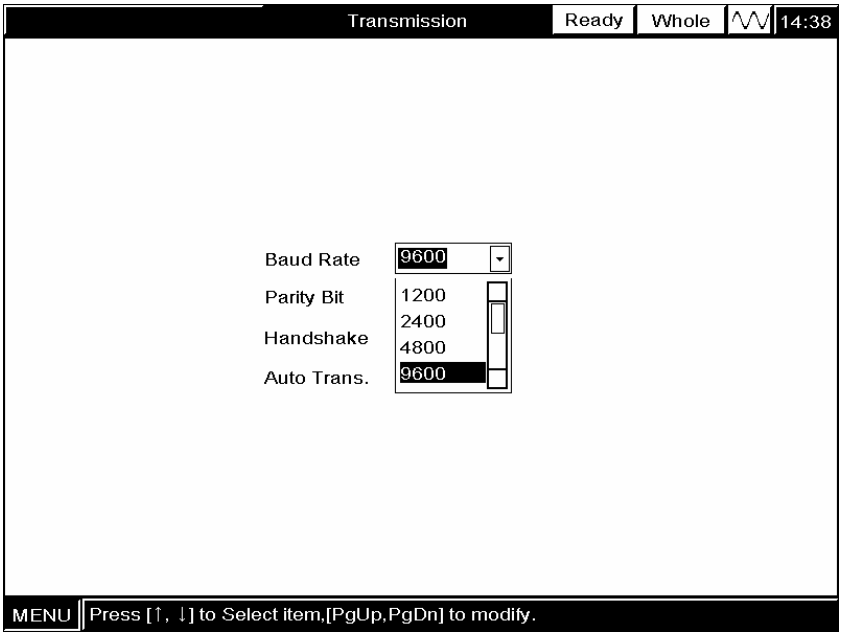


Figure 5-19 Selecting baud rate

5.5.3 Selecting parity

Three parity options are available: "**Odd**", "**Even**" and "**None**" (default). To select the desired option, ***SELECT*** the desired rate ***from the*** "**Parity**"***pull-down list***, as Figure 5-20 shows***.***

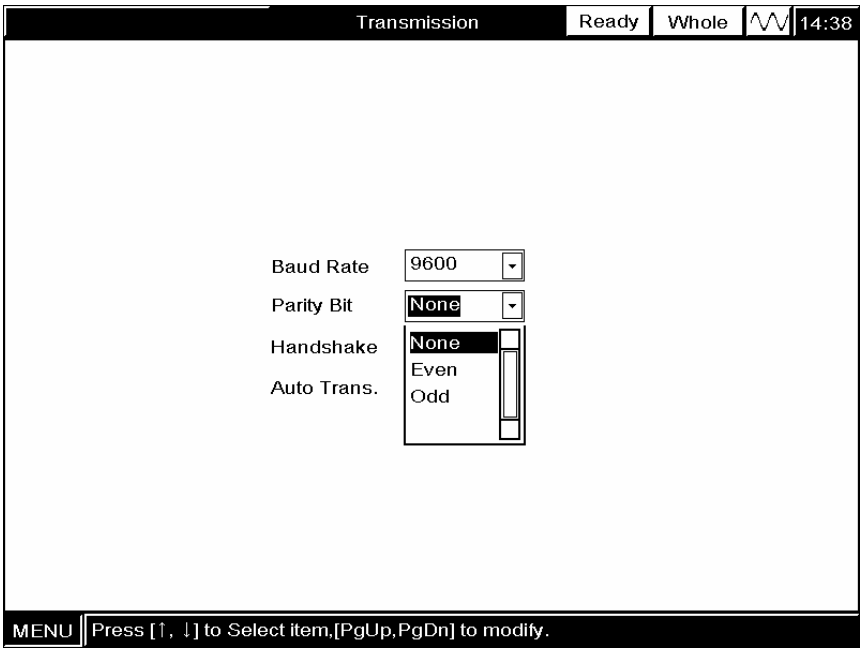


Figure 5-20 Selecting parity check

5.5.4 Enabling/disabling handshake

If the "**Handshake**"function is enabled, the analyzer will send a handshake signal to the host and wait for the response. If the host does not respond in 8 seconds, the analyzer will abort the transmission and alarm you for a transmission error. If the "**Handshake**" function is disabled, the analyzer will transmit the data without confirming the communication link. To enable (or disable) the "**Handshake**" function, ***SELECT*** "**Yes**" (or "**No**") ***from the*** "**Handshake**" ***pull-down list***, as Figure 5-21 shows. The "**Handshake**" function is disabled by default.

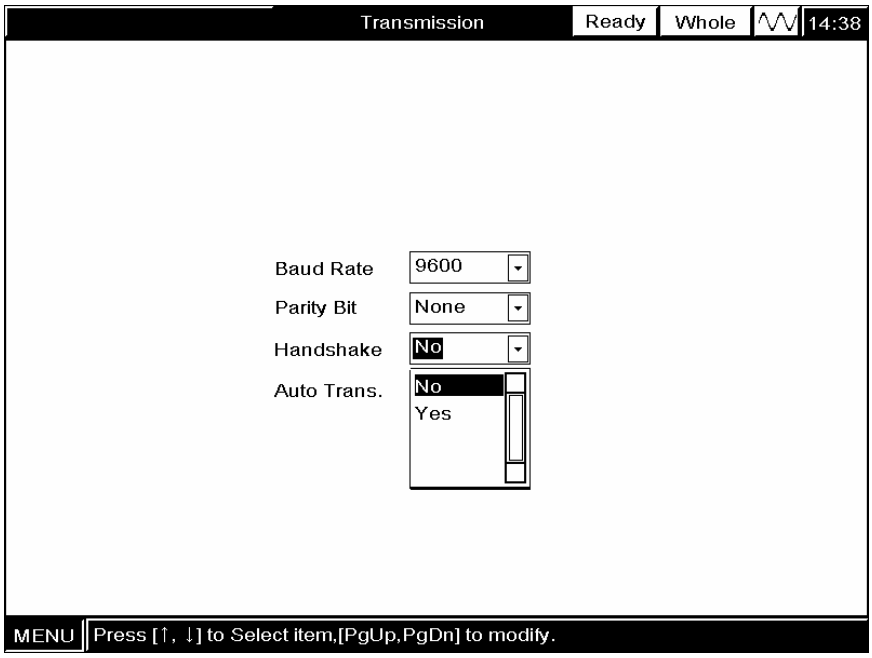


Figure 5-21 Enabling/disabling handshake

5.5.5 Enabling/disabling auto transmission

When the auto transmission function is enabled, the analyzer will automatically transmit the analysis result to the host once the analysis is finished. To enable (or disable) the auto transmission function, ***SELECT*** "**ON**" (or "**OFF**") ***from the*** "**Auto Trans.**" ***pull-down list***, as Figure 5-22 shows.

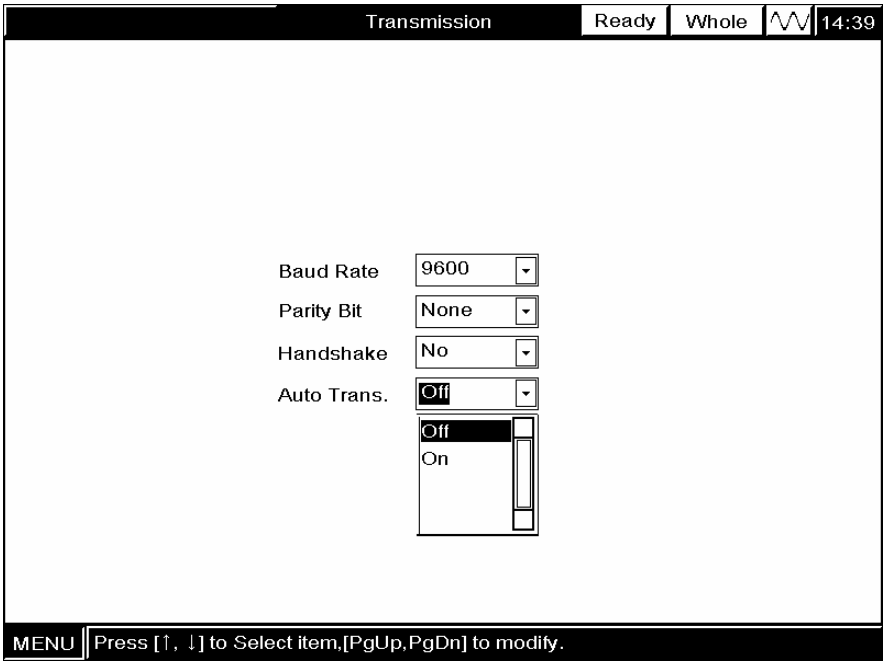


Figure 5-22 Enabling/disabling auto transmission

5.5.6 Exiting the “Transmission” screen

Press [MENU] to exit to the system menu or [MAIN] to exit to the “**Count**” screen, and the changes will be saved automatically.

5.6 Setting system time (Date & Time)

The "**Date & Time**" screen is where you set the system date and time.

5.6.1 Entering "Date & Time" screen

Press [MENU] to enter the system menu.

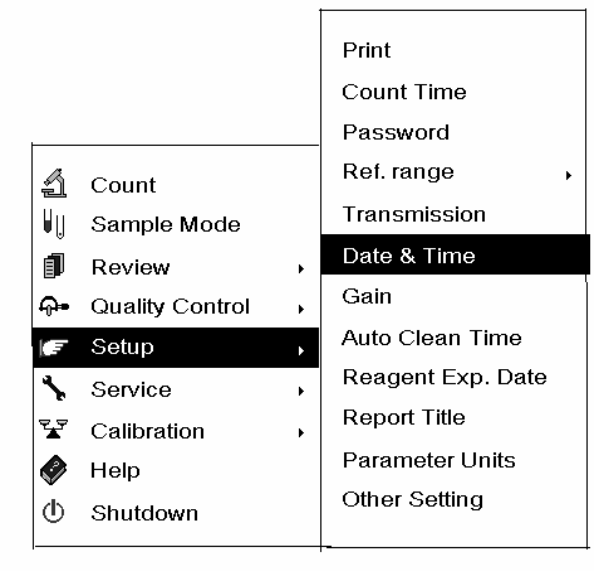


Figure 5-23 System menu

SELECT "**Setup→Date & Time**" (Figure 5-23) to enter the "**Date & Time**" screen (Figure 5-24).

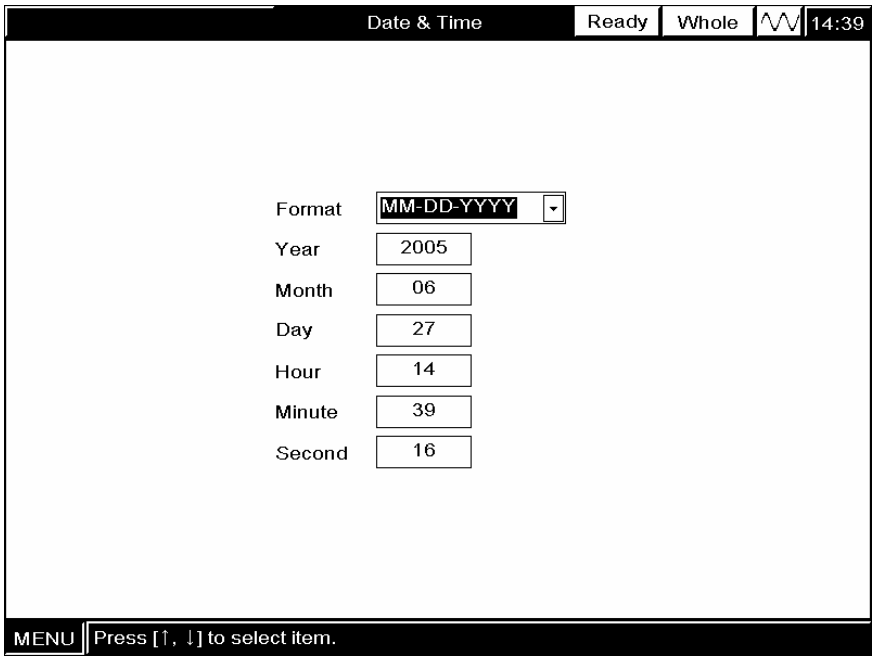


Figure 5-24 "Date & Time" screen

5.6.2 Selecting date format

Three date formats are available: "**YYYY-MM-DD**", "**MM-DD-YYYY**" and "**DD-MM-YYYY**". To select the desired format, ***SELECT*** the desired format ***from the*** "**Format**"***pull-down list,*** as Figure 5-25 shows.

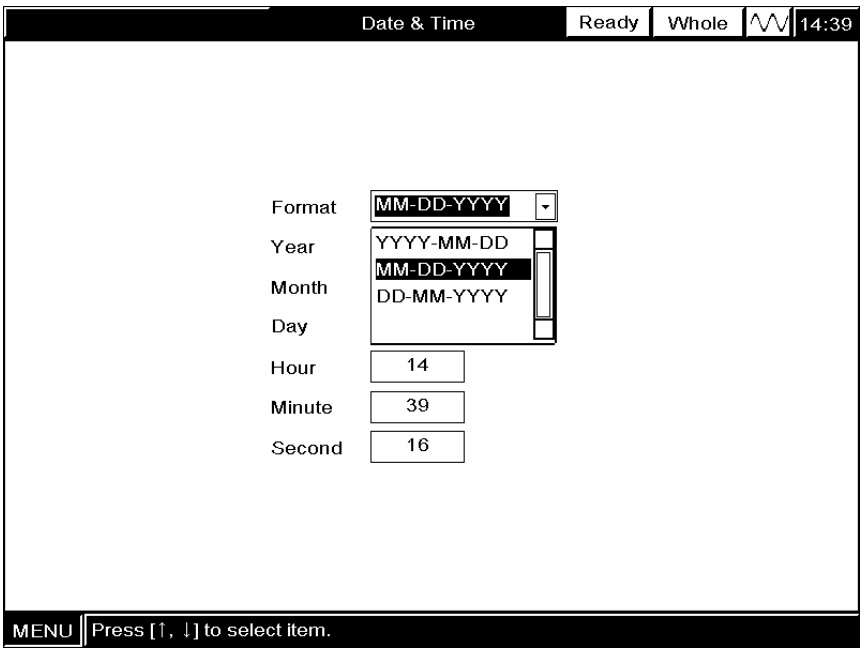


Figure 5-25 Selecting date format

5.6.3 Setting system time

Respectively ***ENTER*** desired numbers into the " **Year**", "**Month**", "**Day**", "**Hour**", "**Minute**" and "**Second**" boxes.

5.6.4 Exiting the "Date & Time" screen

Press [MENU] to exit to the system menu or [MAIN] to exit to the "**Count**" screen, and the changes will be saved automatically.

5.7 Gain

The ”**Gain**” screen is where you view and/or set (if you have the administrator password) gains of the “**WBC (Whole Blood)**”, “**WBC (Predilute)**”, “**RBC**” and “**HGB**” gains.

5.7.1 Entering the “Gain” screen

Press [MENU] to enter the system menu.

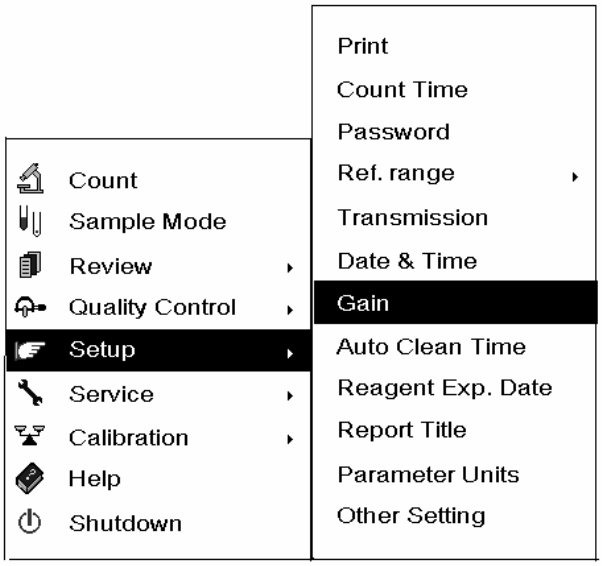


Figure 5-26 System menu

SELECT “**Setup→Gain**”(Figure 5-26) shows to enter the ”**Gain**” screen (Figure 5-27).

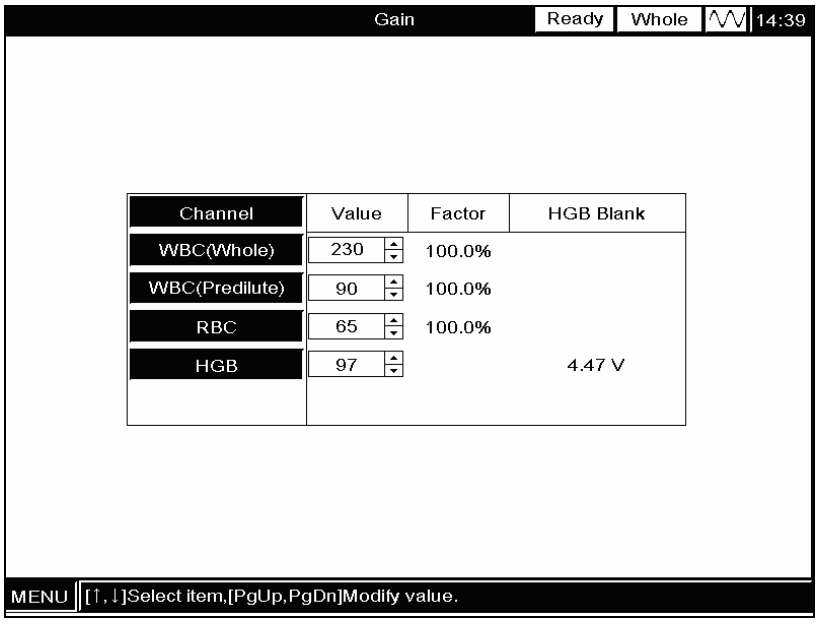


Figure 5-27 “Gain” screen

5.7.2 Setting WBC channel gain

You can adjust the shape of the WBC histogram by adjusting the gain of the WBC channel.

■ When WBC histograms of most samples are similar to Figure 5-28, it implies too small a WBC gain and you need to increase the gain appropriately.

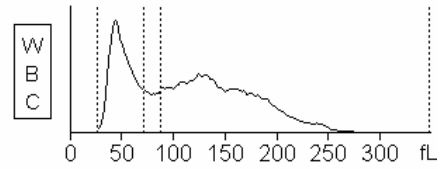


Figure 5-28 WBC gain too small

■ When WBC histograms of most samples are similar to Figure 5-29, it implies too large a WBC gain and you need to decrease the gain appropriately.

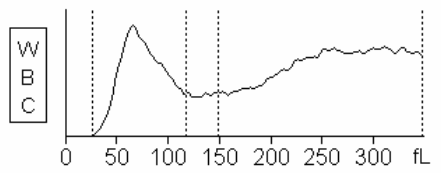


Figure 5-29 WBC gain too large

To increase (or decrease) the gain

1. Enter the administrator password as introduced in **Chapter 5.4.1**.
2. Enter the ”**Gain**” screen and ***ENTER*** the desired gain into the “**WBC (Whole)** ”**,** as Figure 5-30 shows, or “**WBC (Predilute)**”, as Figure 5-31 shows.

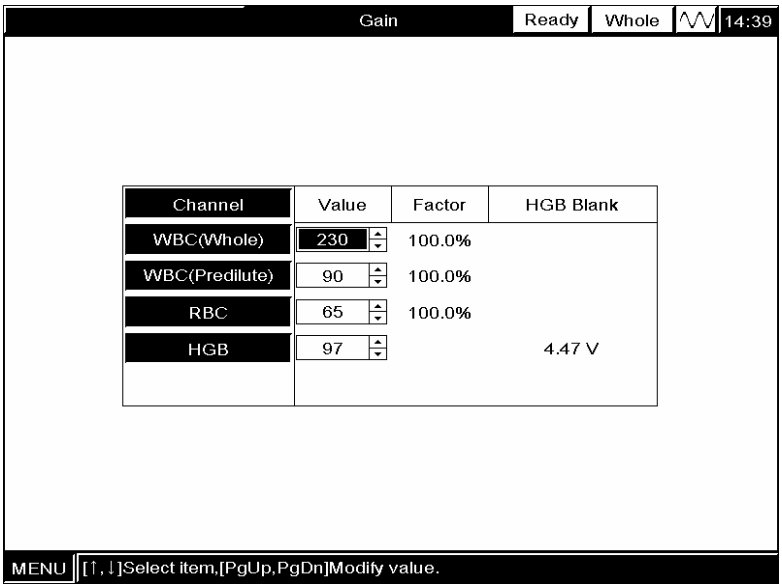


Figure 5-30 Setting WBC（Whole）gain

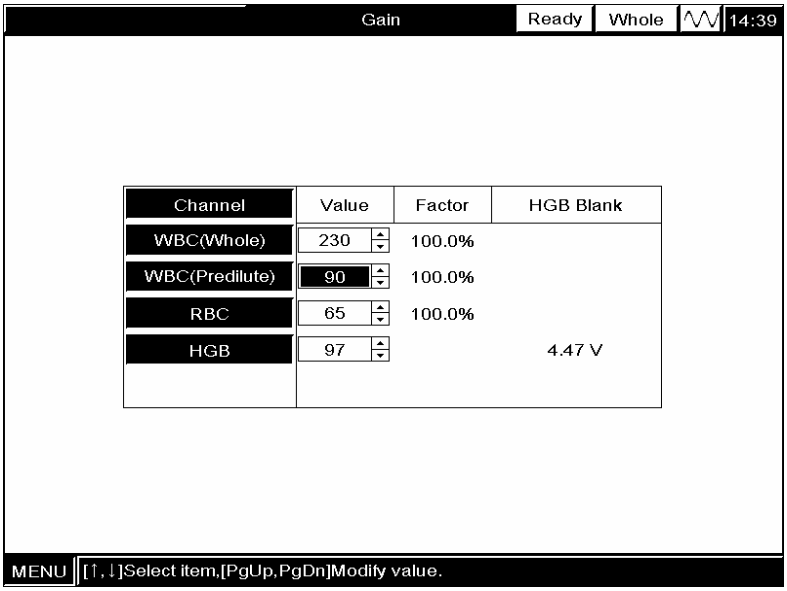


Figure 5-31 Setting WBC（Predilute）gain

5.7.3 Setting the RBC gain

If the MCV results of most calibration or QC runs deviate from the expected result by 6%, you need to follow the rule below to change the RBC gain to adjust the MCV results.

Assume the expected MCV result is 90.0fL and the obtained MCV result is 82.0fL.
Then

$$\frac{\text{ExpectedMCV}}{\text{ActualMCV}} \times 100\% = \frac{90.0}{82.0} \times 100\% = 109.8\%$$

1. Enter the administrator password as introduced in **Chapter 5.4.1**.
2. Enter the “**Gain**” screen and ***ENTER*** a number into the ”**RBC**” box, as Figure 5-32 shows, so that RBC “**Factor**” is as close to 109.8% as possible.

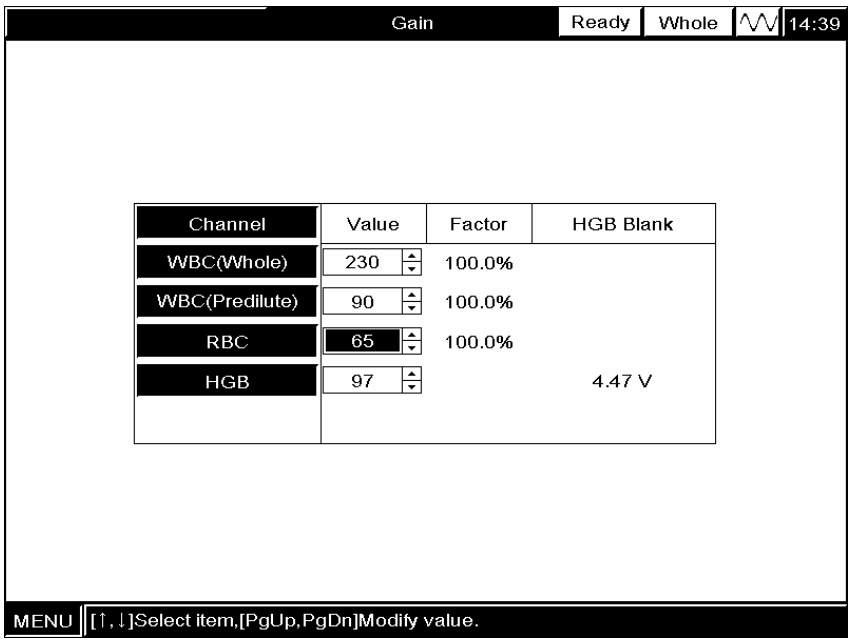


Figure 5-32 Setting RBC gain

5.7.4 Setting HGB channel gain

You can adjust the HGB blank voltage by adjusting the HGB gain. Normally the HGB blank voltage should be within 3.4 - 4.8 V (4.5V is recommended). To set the HGB channel gain,

1. Enter the administrator password as introduced in **Chapter 5.4.1**.
2. Enter the “**Gain**” screen and ***ENTER*** the desired gain into the ”**HGB**” box so that the HGB voltage falls between 3.4 - 4.8 V, as Figure 5-33 shows.

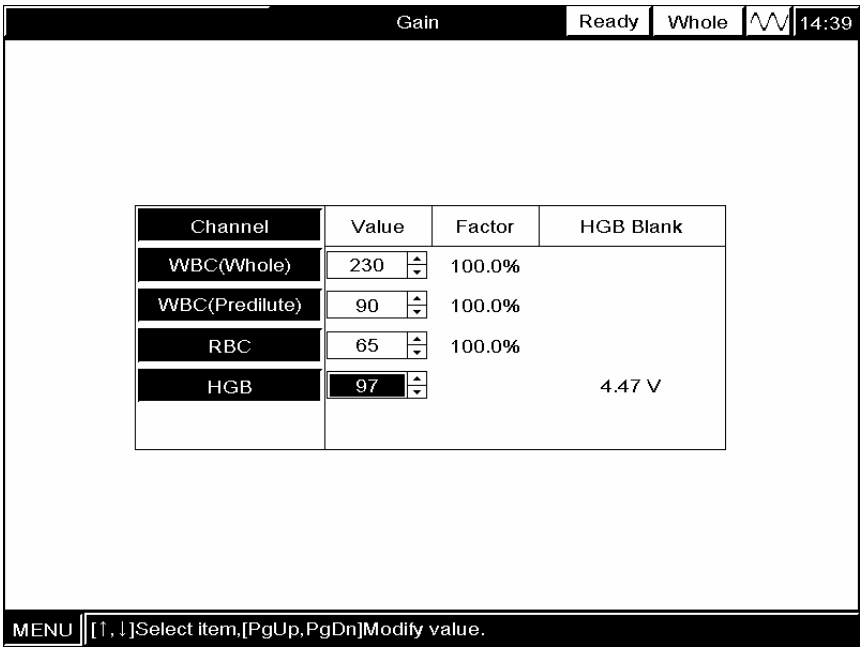


Figure 5-33 Setting HGB gain

5.7.5 Exiting the "Gain" screen

Press [MENU] or [MAIN] to exit the "**Gain**" screen and a message box will pop up to ask you save the changes, as Figure 5-34 shows.

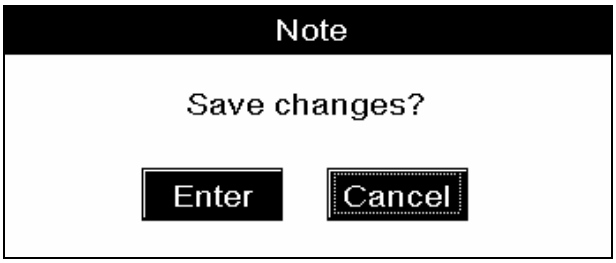


Figure 5-34 A message box to confirm the changes

CLICK "**Enter**" to save the changes and exit to the system menu; ***CLICK*** "**Cancel**" to exit to the system menu or the "**Count**" screen without saving the changes.

5.8 Auto Clean Time

The "**Auto Clean Time**" screen is where you set the interval for auto cleaning of the fluidic lines. The valid interval is 2 - 24 hours and the default interval is 4 hours. To set the interval, Press [MENU] to enter the system menu.

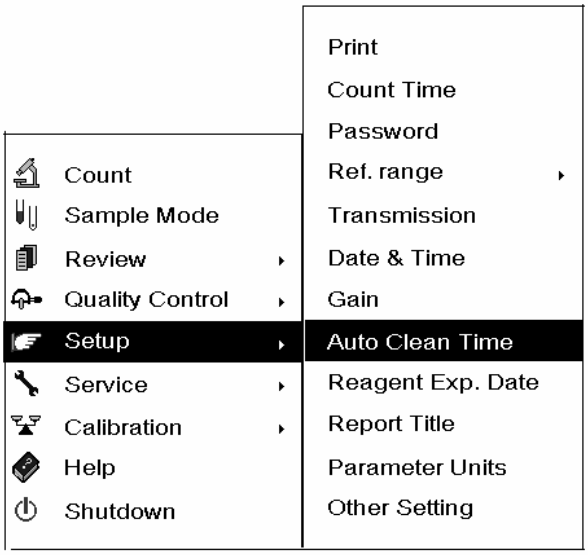


Figure 5-35 System menu

SELECT "**Setup→Auto Clean Time**" (Figure 5-35) to enter the "**Auto Clean Time**" screen (Figure 5-36).

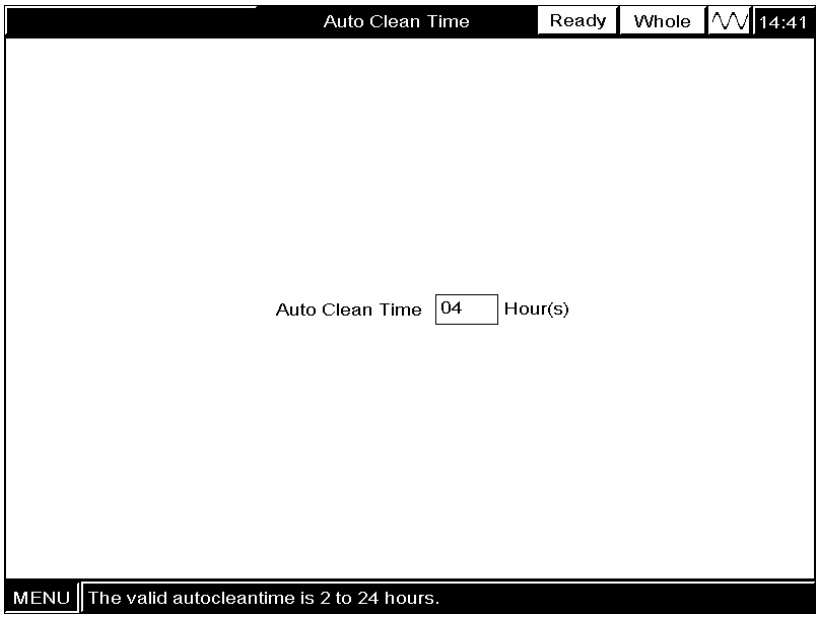


Figure 5-36 "Auto Clean Time" screen

ENTER the desired interval. Press [MENU] to exit to the system menu or [MAIN] to exit to the "**Count**" screen, and the changes will be saved automatically.

5.9 Reagent Exp. Date

The ”**Reagent Exp. Date**” screen is where you set expiration dates for the diluent, rinse and lyse. The analyzer will alarm you for expired reagents when the system time exceeds any of the three expiration dates.

5.9.1 Entering the “Reagent Exp. Date” screen

Press [MENU] to enter the system menu.

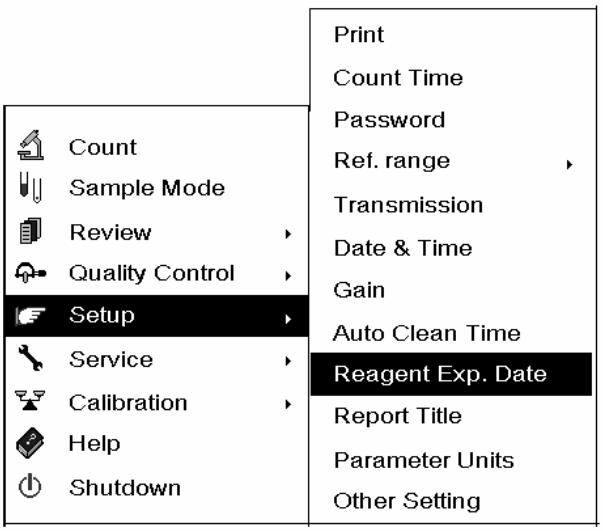


Figure 5-37 System menu

SELECT ” **Setup→ Reagent Exp. Date**” (Figure 5-37) to enter the ”**Reagent Exp. Date**” screen (Figure 5-38).

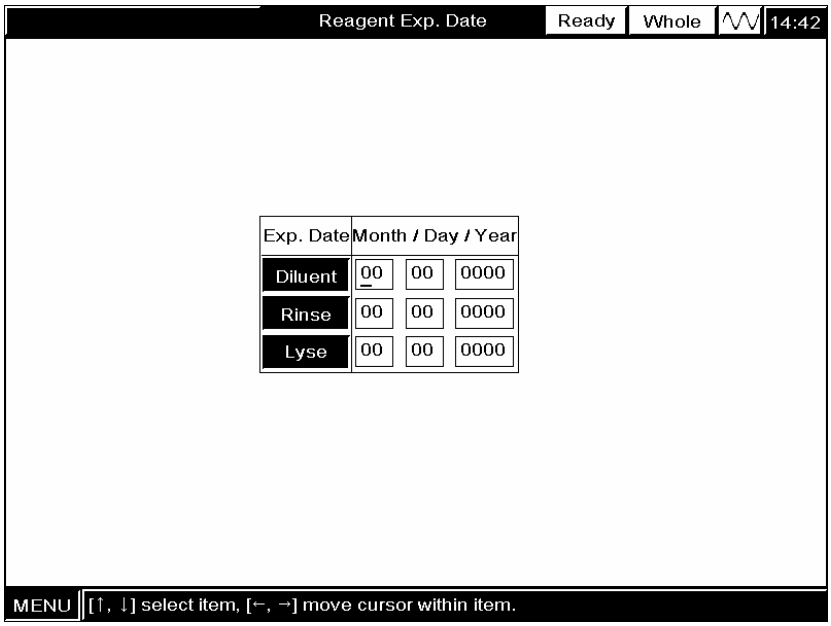


Figure 5-38 “Reagent Exp. Date” screen

5.9.2 Setting the expiration date

ENTER the desired expiration dates into the ” **Diluent**”, “**Rinse**” and ” **Lyse**” boxes.

NOTE

- **For any reagent, the entered expiration date should be either the expiration date printed on the labeling or the open-container expiration date, whichever is earlier.**
- **The open-container expiration date is calculated as follows: the date that container is opened + the open-container stability days.**

5.9.3 Exiting the “ReagentExp. Date” screen

Press [MENU] or [MAIN] to exit the ” **ReagentExp. Date**” screen and a message box will pop up to ask you save the changes, as Figure 5-39 shows.

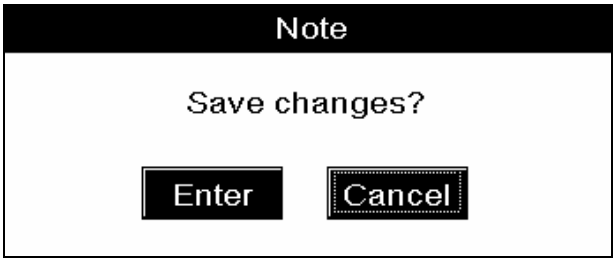


Figure 5-39 A message box to confirm the changes

- ***CLICK*** “**Enter**” to save the changes and exit to the system menu or the “**Count**” screen;
- ***CLICK*** “**Cancel**” to abort the changes and exit to the system menu or the “**Count**” screen.

5.10 Report Title （external keyboard required）

The “**Report Title**” screen is where you set the title of the report to be printed. To set the report title,

Press [MENU] to enter the system menu.

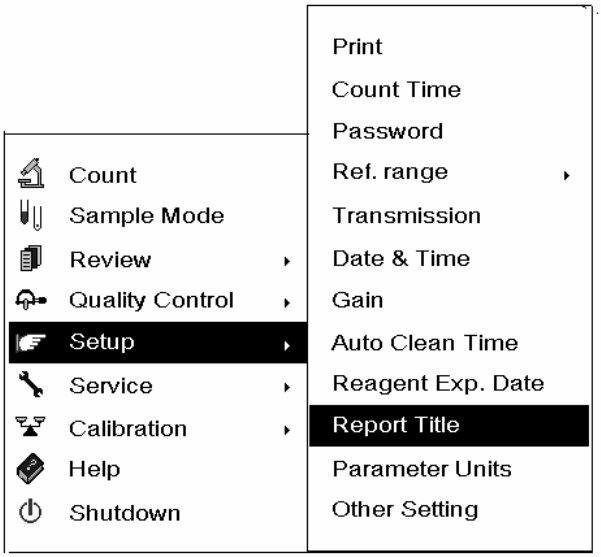


Figure 5-40 System menu

SELECT “**Setup→Report Title**”(Figure 5-40) to enter the ”**Report Title**” screen (Figure 5-41).

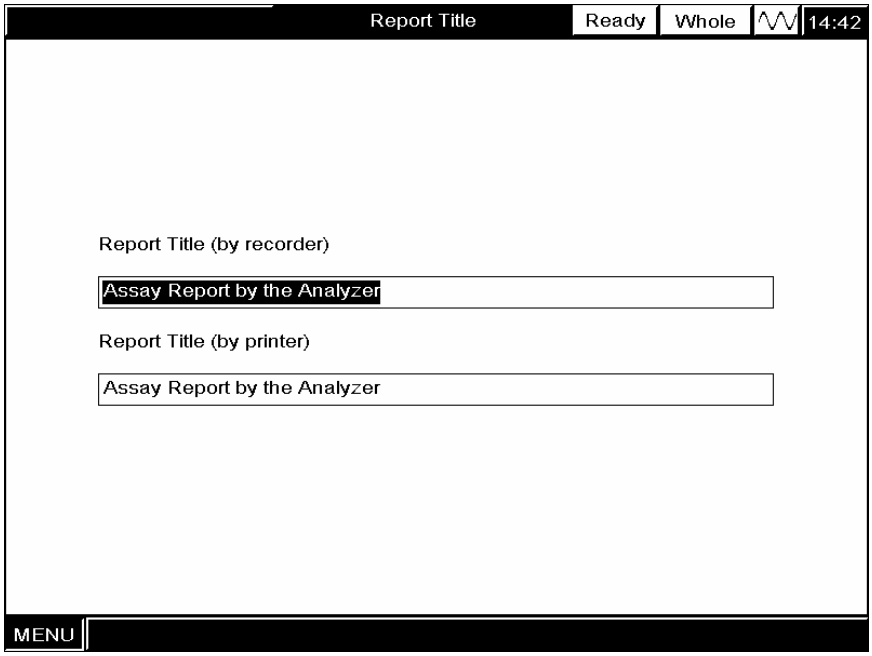


Figure 5-41 “Report Title” screen

ENTER the desired title in the ”**Report Title (by recorder)** ” or ” **Report Title (by printer)** ” box, depending on the printing device you choose to print out the report. Press [MENU] or [MAIN] to save the changes and exit to the system menu or the system menu or the “**Count**” screen.

NOTE

- **To correct any erroneous entry, *DELETE* the wrong character.**

5.11 Parameter Units

The "**Parameter Units**" screen is where you view and/or set (if you have the administrator password) the reporting units of the parameters.

See Table 5-2 for the available units for every parameter groups. Note that if you choose g/L or g/dL for the HGB/MCHC group, the MCH unit will automatically change to pg and its reporting format will be ***.*; if you choose mmol/L for the HGB/MCHC group, the MCH unit will automatically change to fmol and its reporting format will be **.**.

Table 5-2 Reporting unit

Parameter group	Reporting format	Reporting unit	Remarks
WBC	***.*	10^9/L	Default
Lymph#	***.*	10^3/uL	
Mid#	****	10^2/uL	
Gran#	***.*	/nL	
Lymph%	**.*	%	Default
Mid%			
Gran%			
HGB	***	g/L	Default
MCHC	**.*	g/dL	
	**.*	mmol/L	
RBC	*.**	10^{12}/L	Default
	*.**	10^6/uL	
	***	10^4/uL	
	*.**	/pg	
HCT	**.*	%	Default
	.***	L/L	
MCV	***.*	fL	Default
RDW-SD	***.*	um^3	
RDW-CV	**.*	%	Default
PLT	****	10^9 /L	Default
	****	10^3 /uL	
	***.*	10^4 /uL	
	****	/nL	
MPV	**.*	fL	Default

	**.*	um^3	
PDW	**.*	None	Default
PCT	.***	%	Default
	*.**	mL/L	

5.11.1 Entering the “Parameter Units” screen and viewing the settings

Press [MENU] to enter the system menu.

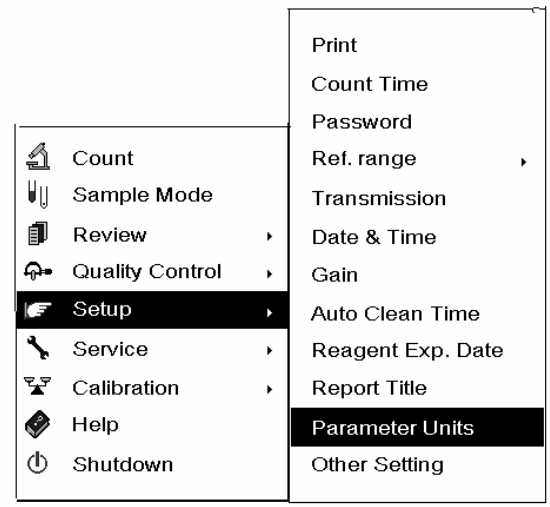


Figure 5-42 System menu

SELECT ”**Setup→ Parameter Units**” (Figure 5-42), to enter the “**Parameter Units**” screen (Figure 5-43).

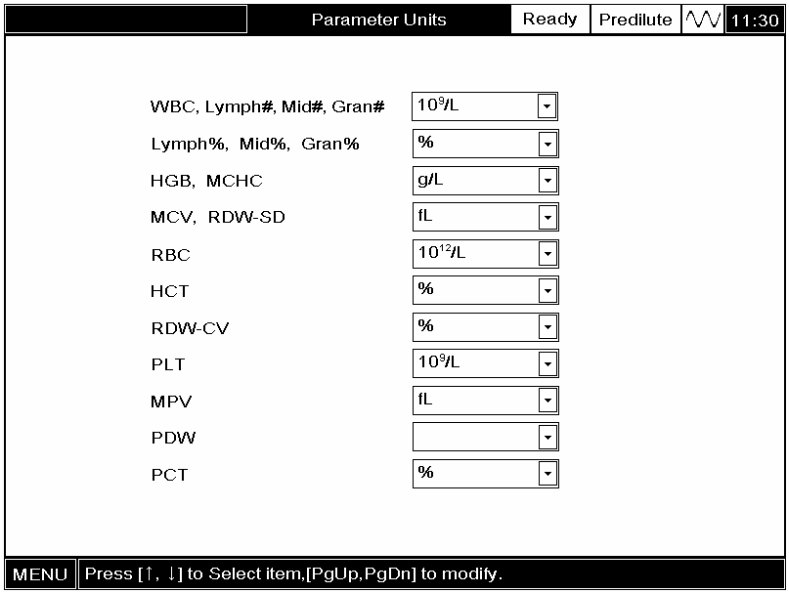


Figure 5-43 “Parameter Units” screen

5.11.2 Setting reporting units

1. Enter the administrator password as instructed in **Chapter 5.4.1**.
2. Enter the "**Parameter Units**" screen.
3. ***SELECT*** the desired unit ***from*** the corresponding ***pull-down list*** (e.g. RBC in Figure 5-44).

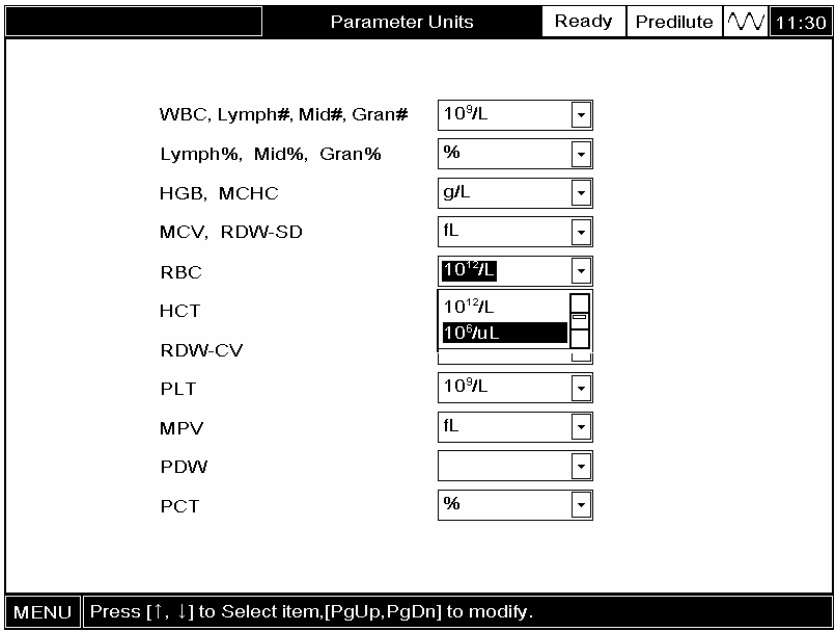


Figure 5-44 Selecting a unit for RBC

5.11.3 Exiting the "Parameter Units" screen

Press [MENU] or [MAIN] to exit to the system menu or the "**Count**" screen and the changes will be saved automatically.

5.12 Other

The "**Other**" screen is where you define miscellaneous system settings.

5.12.1 Entering the "Other" screen

Press [MENU] to enter the system menu.

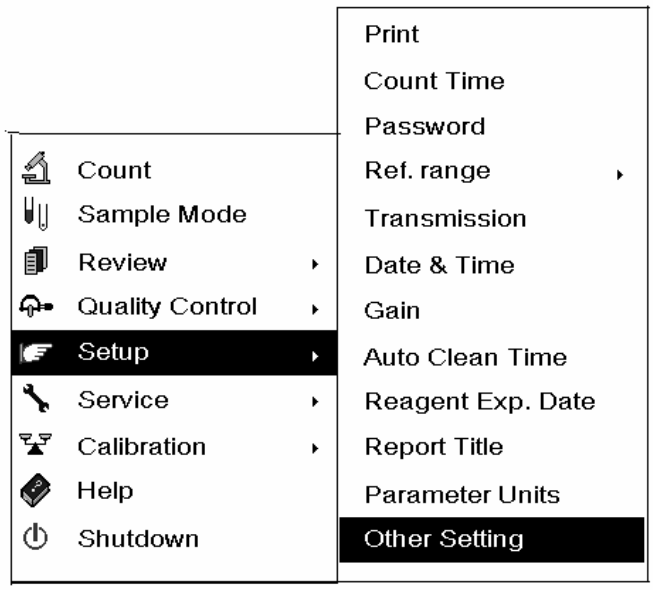


Figure 5-45 System menu

SELECT "**Setup→Other**"(Figure 5-45) to enter the "**Other**" screen (Figure 5-46).

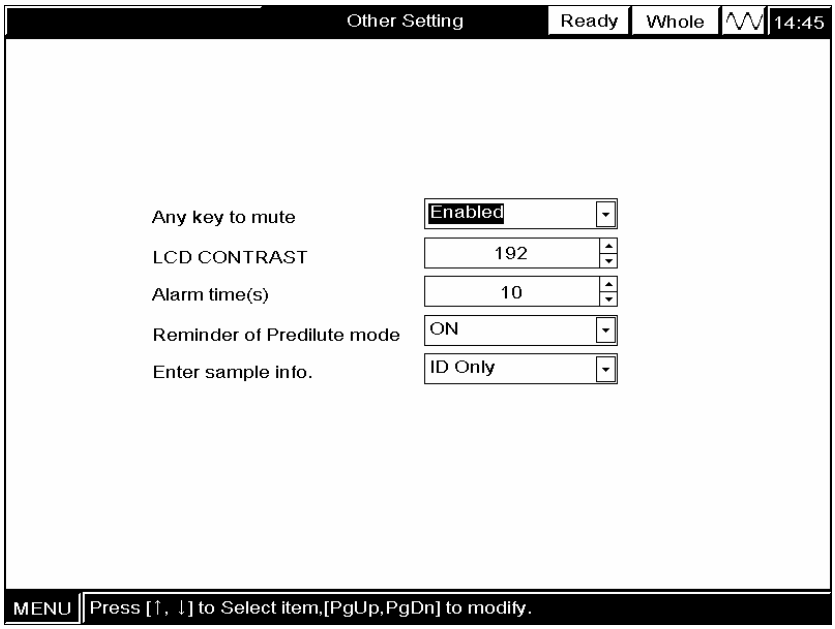


Figure 5-46 "Other" screen

5.12.2 Muting the Beeper

The analyzer beeps when an error is present. You can mute the beeper by pressing any key (except for the aspirate key), as long as the ”**Any key to mute**” function is enabled. To enable (or disable) the function, ***SELECT*** ”**ON**” (or ” **OFF**”) ***from the*** ”**Any key to mute**” ***pull-down list****,* as Figure 5-47 shows. Note that if you have disabled the ”**Any key to mute**” function, the analyzer will keep beeping for the pre-set alarm time or until the error is removed.

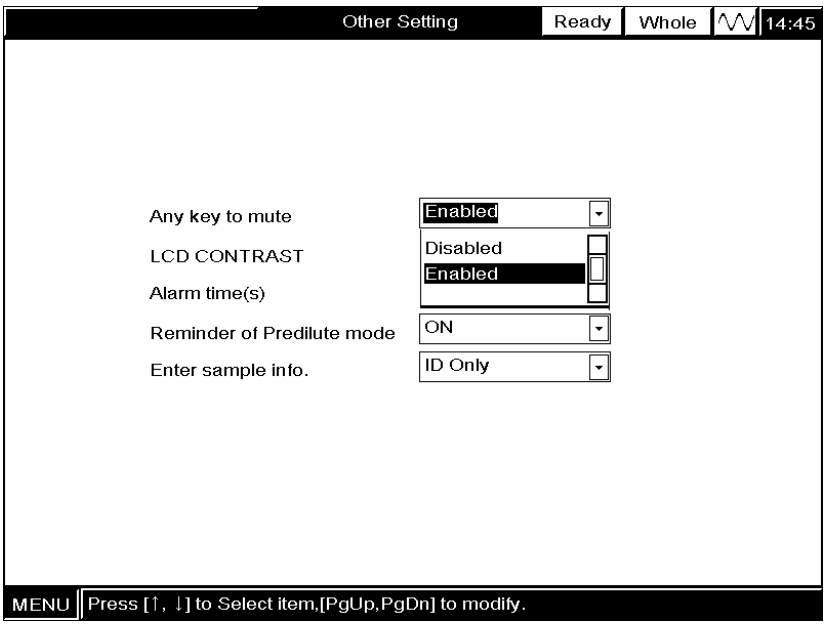


Figure 5-47 Enabling/disabling “Any key to mute” function

5.12.3 Setting LCD contrast

The analyzer divides the LCD contrast into 256 levels (level 0 - level 255) and the higher the level, the higher the contrast. To select a desired LCD contrast level, ***ENTER*** the desired number into the ”**LCD Contrast**” box（Figure 5-48）

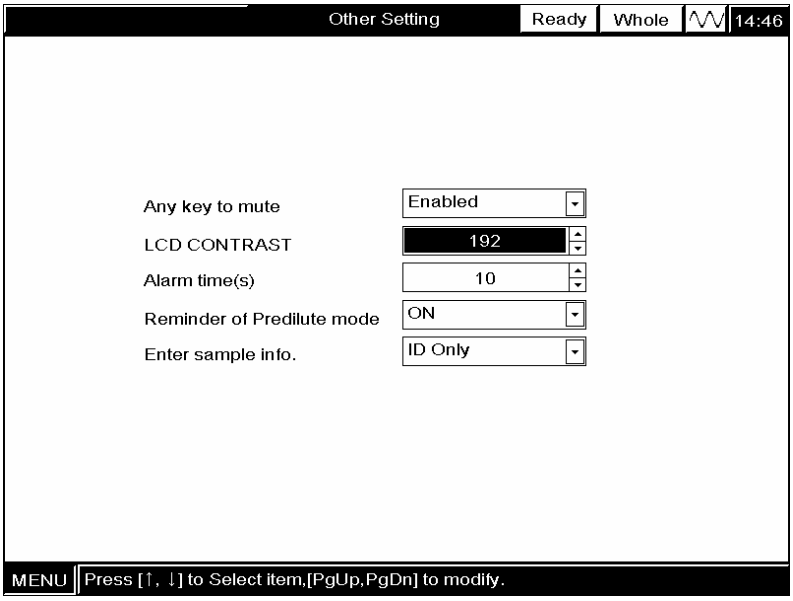


Figure 5-48 Selecting LCD contrast

5.12.4 Setting alarm time for error messages

The alarm time of the errors listed in Table 5-3 can be set to 2 - 120 seconds. When the pre-set alarm times out, both the alarm sound and the corresponding error message will disappear.

Table 5-3 Errors with adjustable display time

No.	Error	No.	Error	No.	Error
1	Communication error	2	Scanner error	3	Scanner communication error
4	Ambient temperature abnormal	5	Background abnormal	6	HGB error
7	HGB adjust	8	WBC clog	9	WBC bubble
10	RBC Clog	11	RBC bubble	12	Printer connection error
13	Printer out of paper	14	Recorder too hot	15	Recorder communication error
16	Press bar up	17	Recorder out of paper		

To set the display time, ***ENTER*** the desired time into the "**Alarm time (s)**" box.

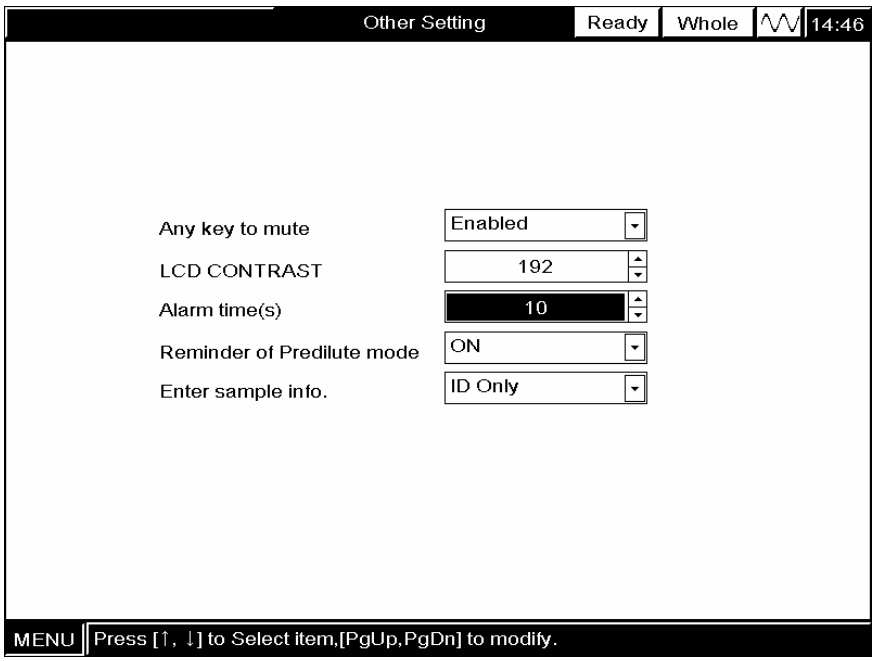


Figure 5-49 Selecting alarm time

5.12.5 Reminder of Predilute mode

If you have enabled the "**Reminder of Predilute mode**" function and selected the Predilute mode, the analyzer will ask you to confirm the selection.

To enable (or disable) the "**Reminder of Predilute mode**" function, ***SELECT*** "**ON**"(or "**OFF**") ***from*** the "**Reminder of Predilute mode**" ***pull-down list***.

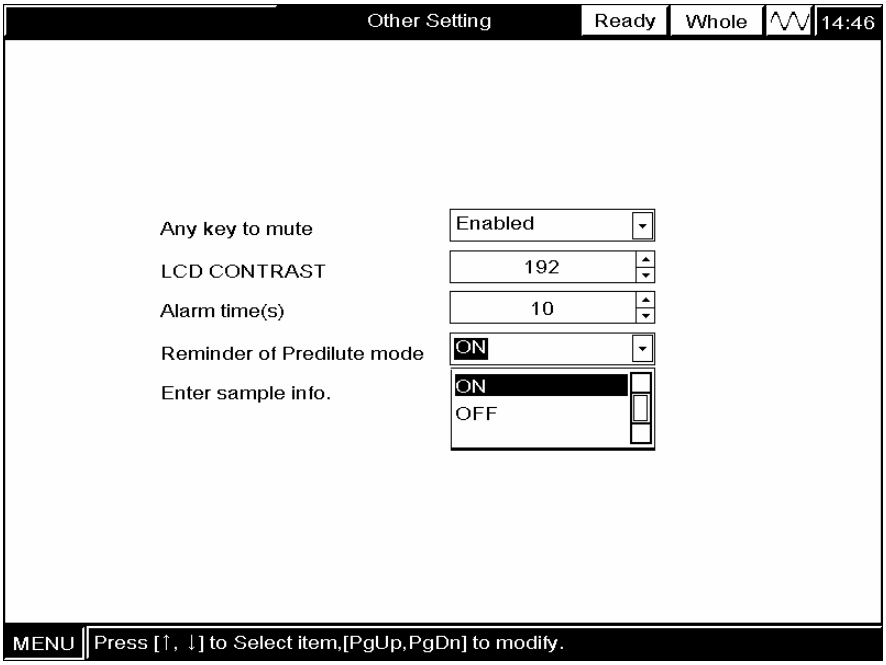


Figure 5-50 Enabling/disabling the "Reminder of Predilute mode" function

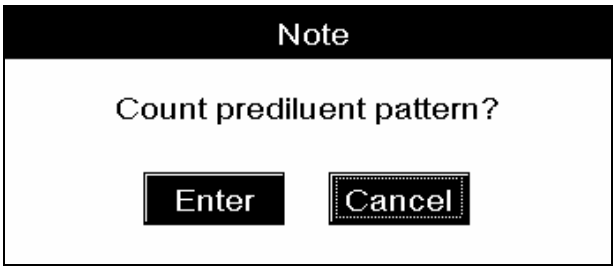


Figure 5-51 A message box to confirm the predilute mode

5.12.6 Selecting how to enter sample information

If you have entered the administrator password, you can select in which way to enter the sample information, "**ID only**" (to enter the sample ID only) or "**All Info.**"(to enter all the sample information), by selecting "**ID Only**" or "**All Info.**" ***from*** the "**Enter Sample Info.**" ***pull-down list***.（Figure 5-52）

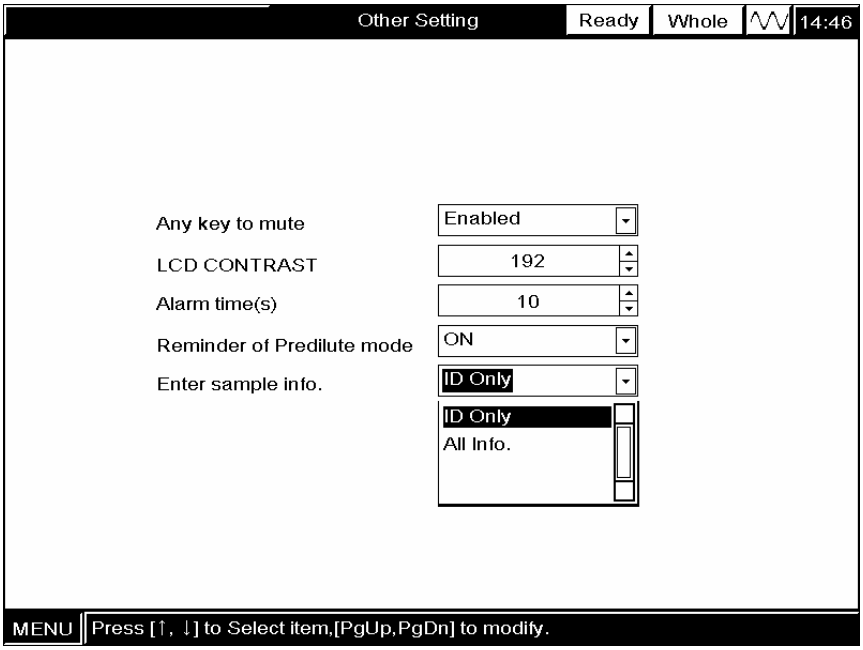


Figure 5-52 Selecting how to enter patient information

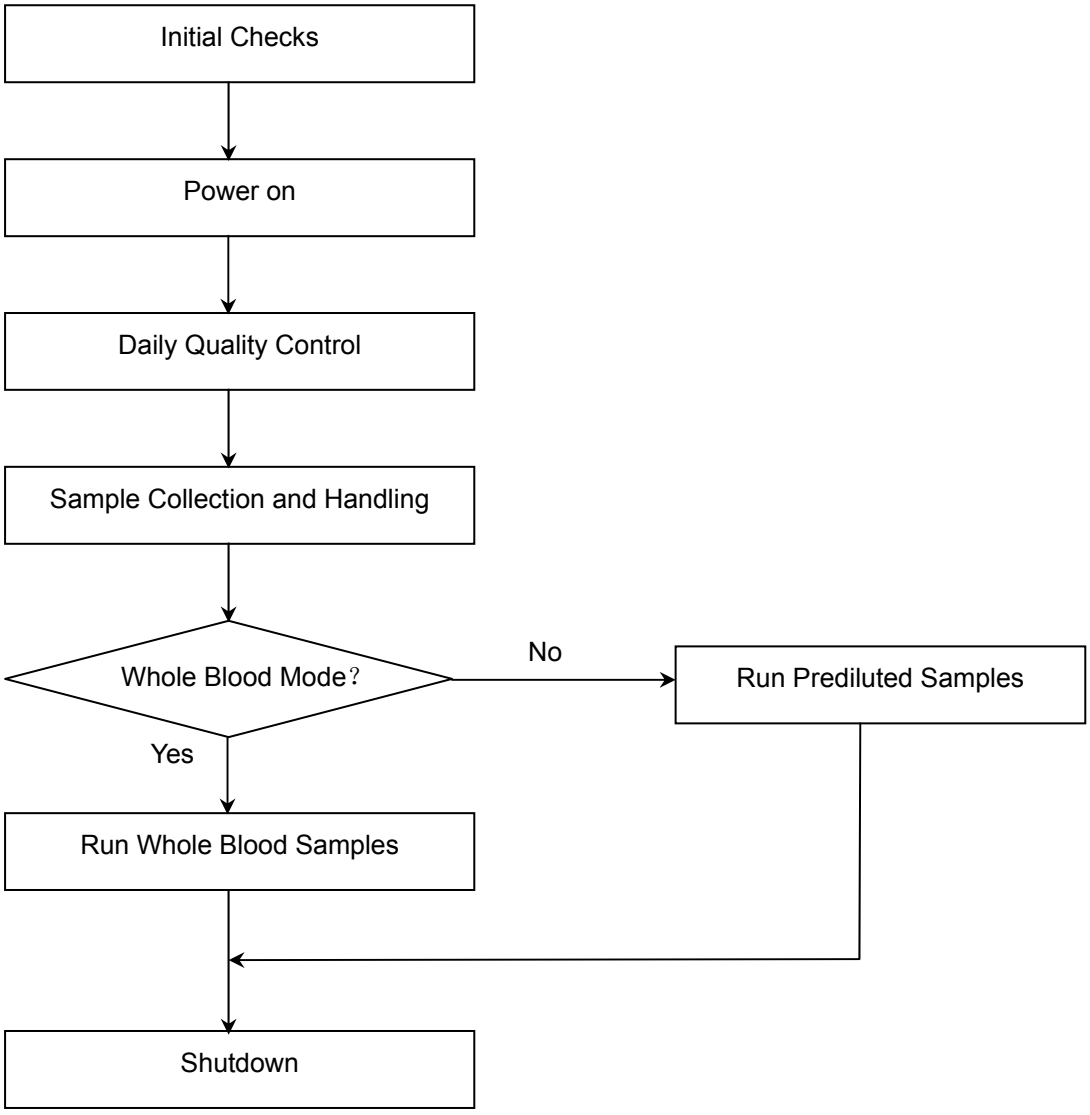
5.12.7 Exiting the "Other" screen

Press [MENU] or [MAIN] to exit to the system menu or the "**Count**" screen and all the changes will be saved automatically.

6 Operating Your Analyzer

6.1 Introduction

This chapter provides step-by-step procedures for operating your analyzer on a daily basis. A flow chart indicating the common daily operating process is presented below.



6.2 Initial Checks

Perform the following checks before turning on the analyzer.

1. Checking the waste container;

2. Check and make sure the container is empty.

- **Samples, controls, calibrators and waste are potentially infectious. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them in the laboratory.**

⚠ WARNING

- **Be sure to dispose of reagents, waste, samples, consumables, etc. according to government regulations.**

3. Checking tubing and power connections ;

■ Check and make sure the diluent, rinse and waste tubes are properly connected and not bent;

■ Check and make sure the power cord of the analyzer is properly plugged into an electrical outlet.

4. Checking the printer (optional) and recorder;

Check and make sure enough printer or recorder paper is installed. Check and make sure the power cord of the printer is properly plugged into an electrical outlet. Check and make sure the printer cable is properly connected to the analyzer.

5. Check keyboard connection.

Check and make sure the keyboard is properly connected to the keyboard interface (marked KB) of the analyzer.

6.3 Power-on

Place the power switch at the back of the analyzer in the ON position (1) to turn on the analyzer. The power indicator light will be illuminated and the screen will display "**Initializing…**".

The analyzer will sequentially initialize the file, hardware and fluidic systems and the whole initializing process lasts 3 to 5 minutes, depending on how the analyzer was previously shut down.

If any error occurs during the initialization, the analyzer will display the error messages in the upper left corner of the screen. You should remove all the errors before running any sample. See **Chapter 11 Troubleshooting Your Analyzer** for solutions.

NOTE

- **Running samples with the abnormal background error present will lead to misleading results.**

6.4 Daily Quality Control

Before running any samples, run the controls. See **Chapter 8 Using the QC Programs** for details.

6.5 Sample Collection and Handling

- **Samples, controls, calibrators and waste are potentially infectious. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them in the laboratory.**

⚠ WARNING

- **Avoid direct contact with blood samples.**
- **Do not re-use disposable products.**

NOTE

- **Be sure to use clean K_2EDTA anticoagulant collection tubes, fused silica glass/plastic test tubes and 20μL borosilicate glass capillary tubes.**

6.5.1 Whole Blood Samples

Collect and handle the whole blood sample as follows:

1. Collect venous blood with a K_2EDTA（1.5 - 2.2mg/ml）anticoagulant collection tube;
2. Rapidly and thoroughly mix the blood with the anticoagulant;

NOTE

- **Be sure to use clean K_2EDTA anticoagulant collection tubes, fused silica glass/plastic test tubes and 20μL borosilicate glass capillary tubes.**
- **For the whole blood samples to be used for WBC differential or PLT count, you shall store them at the room temperature and run them within 8 hours after collection.**
- **If you do not need the PLT, MCV and WBC differential results, you can store the samples in a refrigerator (2℃ - 8℃) for 24 hours. You need to warm the refrigerated samples at room temperature for at least 30 minutes before running them.**
- **Be sure to mix any sample that has been prepared for a while before running it.**

6.5.2 Prediluted Samples

1. Collect and handle the prediluted sample as follows;
2. Press [MENU] and ***SELECT*** "**Mode**" to enter the **"Mode**" screen;
3. ***SELECT*** "**Predilute**" from the "**Sample Mode**" ***pull-down list;***
4. Press [MENU] and ***SELECT*** "**Count**" to enter the "**Count**" screen;
5. Press [DILUENT] and a message box will pop up to instruct you how to dispense the diluent into the sample tube, as Figure 6-1shows;

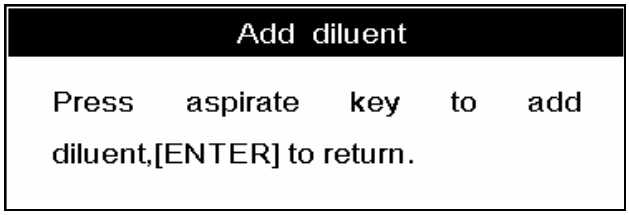


Figure 6-1 A message box showing you how to dispense diluent

6. Present a clean sample tube to the sample probe and make sure the tube is tilted towards the probe, as Figure 6-2 shows, to avoid spills and bubbles. Press the aspirate key to dispense 0.7ml of diluent (the dispensing volume is controlled by the analyzer) into the tube;

Figure 6-2 How to dispense diluent

7. When the dispensing is finished, press [ENTER] to close the message box;
8. Add 20μL of capillary blood to the diluent and shake the tube to mix the sample.

NOTE

- **Be sure to keep dust from the prepared diluent.**
- **After mixing the capillary sample with the diluent, be sure to wait 3 minutes before running the sample.**
- **Be sure to run the prediluted samples within 30 minutes after the mixing.**
- **Be sure to mix any sample that has been prepared for a while before running it.**
- **Be sure to evaluate predilute stability based on your laboratory's sample population and sample collection techniques or methods.**

6.6 Running Whole Blood Samples

Press [MENU] and ***SELECT*** "**Mode**" to enter the "**Sample Mode**" screen, as Figure 6-4 shows.

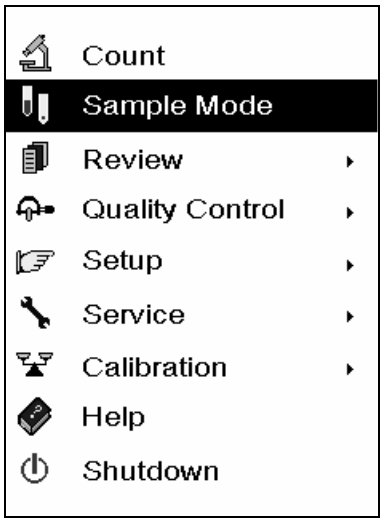


Figure 6-3 System menu

SELECT "**Whole Blood**" from *the "***Sample Mode***" pull-down list*.

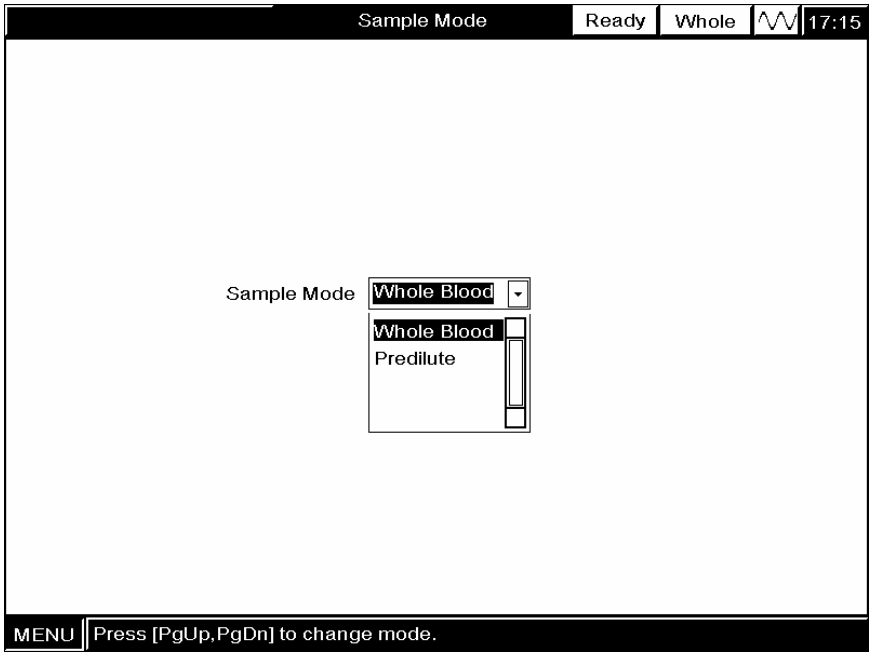


Figure 6-4 "Sample Mode" Screen

Press [MENU] and ***SELECT*** "**Count**" to enter the "**Count**" screen, as Figure 6-5 shows.

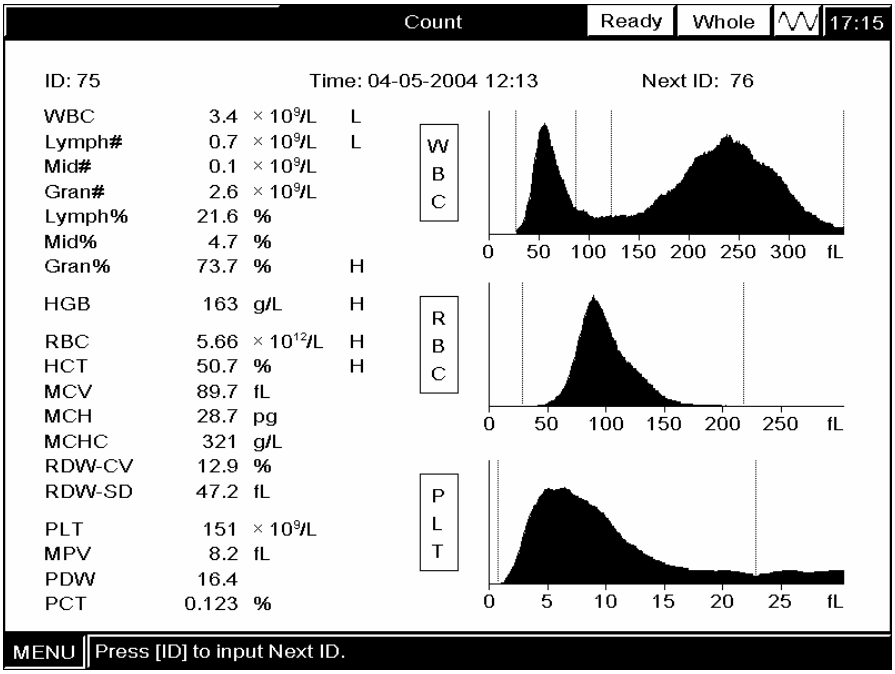


Figure 6-5 "Count" Screen

NOTE

- **Be sure to select proper reference range as instructed in Chapter 5.5 before running the samples. Otherwise, the obtained results may be erroneously flagged.**
- **When switching from the predilute mode to the whole blood mode, the analyzer will automatically wash the fluidic system.**

6.6.1 Entering Sample Information

You can enter the sample information one of the two ways, **ID or All Info.,** depending on the configuration of your analyzer (see **Chapter 5.13** for how to select the entering mode).

All Info. (external keyboard needed)

At the "**Count**" screen, press [ID] and an edit window will pop up, as Figure 6-6 shows.

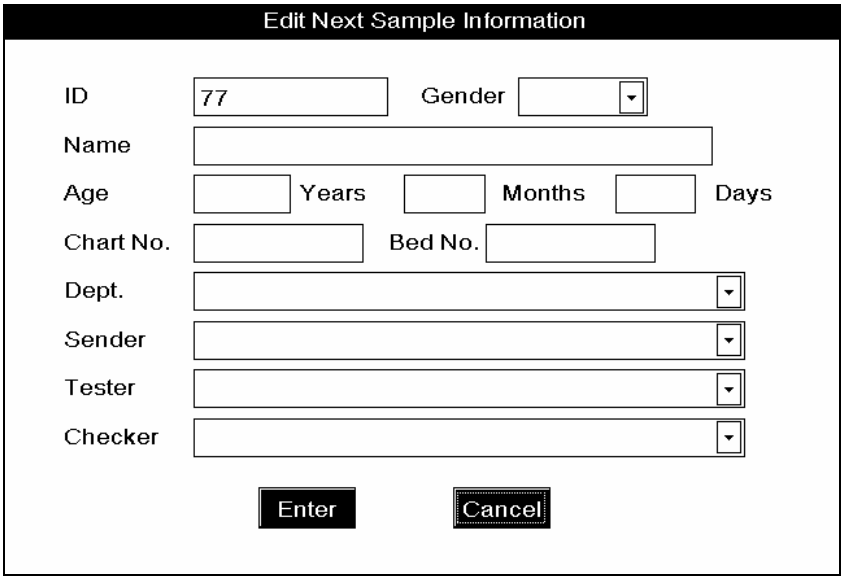


Figure 6-6 Entering all sample information

- Entering sample ID

ENTER the ID number in the "**ID**" box. If you have the bar-code scanner installed, you can simple scan the sample ID into the analyzer.

- Selecting patient gender

SELECT the desired item ***from the "*** **Gender** ***" pull-down list,*** as Figure 6-7 shows. Note that you can select blank in case you are not aware of the patient gender.

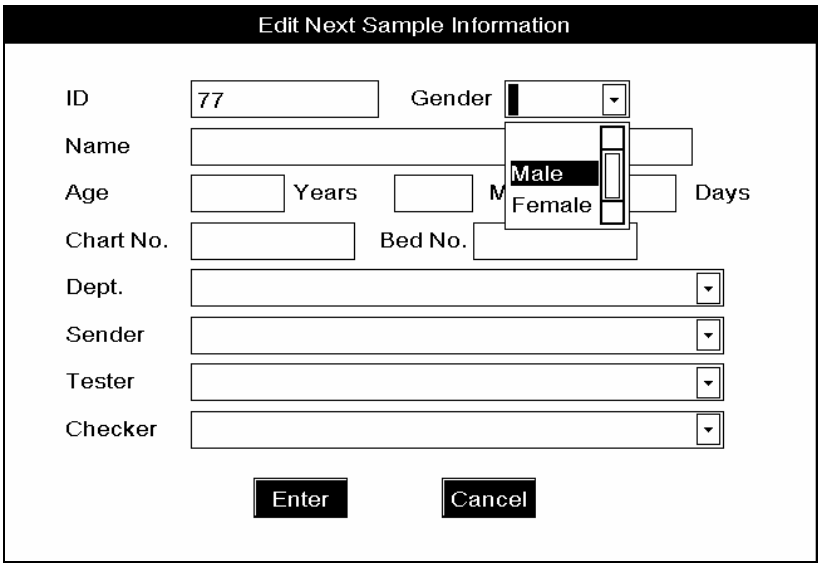


Figure 6-7 How to select the patient gender

- Entering the patient name

ENTER the patient name into the "**Name**" box.

- Entering the patient age

This analyzer provides three ways for you to enter the patient age – in years, in months and in days. The first way is designed for the adult or pediatric patients no younger than one year; the second for the infant patients one month to one year; the third for the neonatal patients no older than 28 days. You can choose only one of the three ways to enter the patient age.

To enter the patient age in years：***ENTER*** the desired number, an integer from 0 to 200, into the "**Years**" box.
To enter the patient age in months：***ENTER*** the desired number, an integer from 0 to 12, into the "**Months**" box.
To enter the patient age in days：***ENTER*** the desired number, an integer from 0 to 31, into the "**Days**" box.

- Entering the chart number

ENTER the number of the patient's medical chart into the "**Chart No.**" box.

- Entering the bed number

ENTER the number of the patient's bed into the "**Bed No.**" box.

- Entering the department name

You can either directly ***ENTER*** the name of the department, from which the sample came, into the "**Department**" box or ***SELECT*** the desired department **from the** "**Department**" **pull-down list** (if there are previously saved departments in the list, as Figure 6-8 shows).

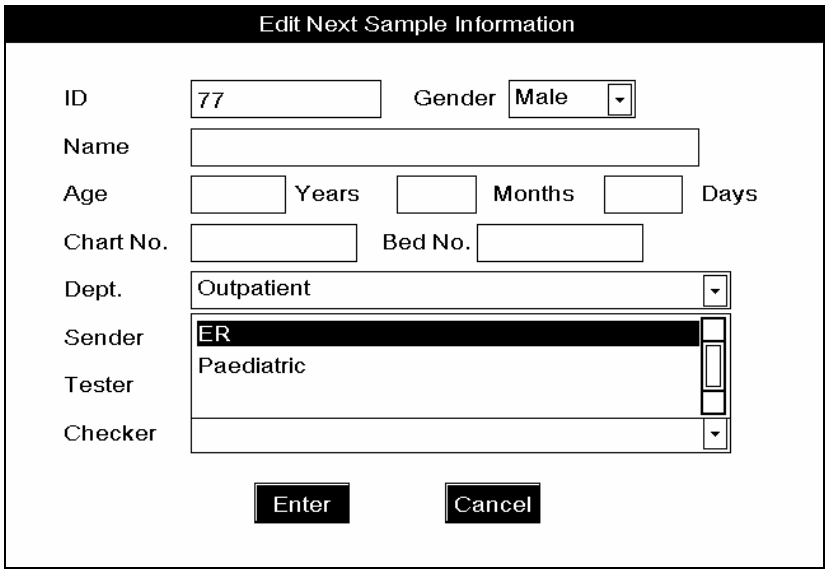


Figure 6-8 How to select department name from the pull-down list

■ Entering the names of the sender, tester and reviewer

To enter the name of the person who sent the sample for analysis, ***ENTER*** the name into the "**Sender**" box or ***SELECT*** the desired name ***from the*** "**Sender**" ***pull-down list*** (if there are previously saved names in the list, as Figure 6-9 shows）; to enter the name of the person who is to run (or has run) the sample, ***ENTER*** the name into the "**Tester**" box or ***SELECT*** the desired name ***from the*** "**Tester**" ***pull-down list*** (if there are previously saved names in the list）; to enter the name of the person who is to review the sample results, ***ENTER*** the name into the "**Reviewer**" box, or ***SELECT*** the desired name ***from the*** "**Reviewer**" ***pull-down list*** (if there are previously saved names in the list）. All the three pull-down lists are capable of saving 30 entered names.

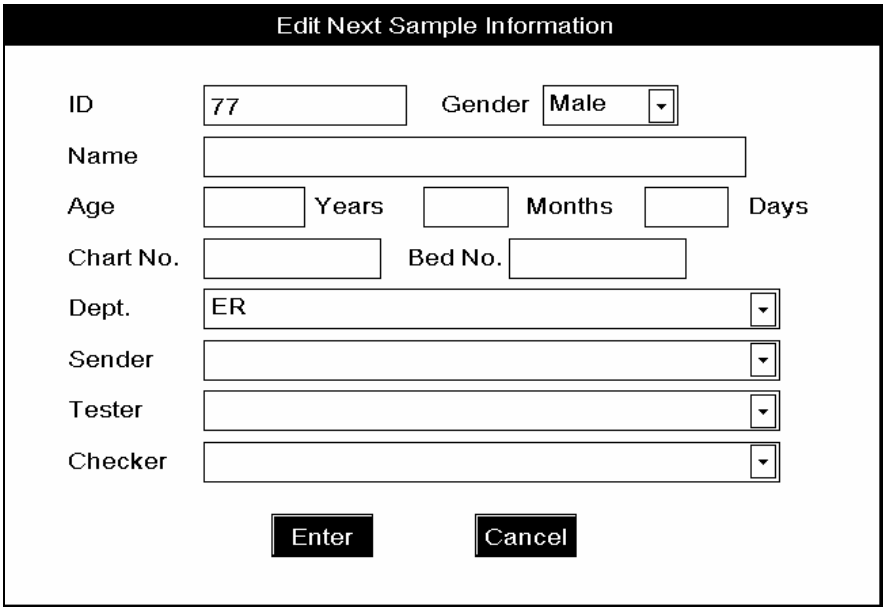


Figure 6-9 Entering names of the sender, tester and reviewer

NOTE

- **To correct an erroneous entry, *DELETE* the wrong character and *ENTER* the correct one.**
- **After entering all the desired information, you may press [F4] on the external keyboard to save the changes and exit to the "Count" screen.**

■ "**Enter**" button

When you have finished entering the all the interested sample information, ***CLICK*** the "**Enter**" button to save the changes and return to the "**Count**" screen.

- "**Cancel**" button

If you do not want to save the entered information, ***CLICK*** the "**Cancel**" button to return to the "**Count**" screen without saving the changes.

ID Only

At the "**Count**" screen, press [ID] and an ID window will pop up, as Figure 6-10 shows.

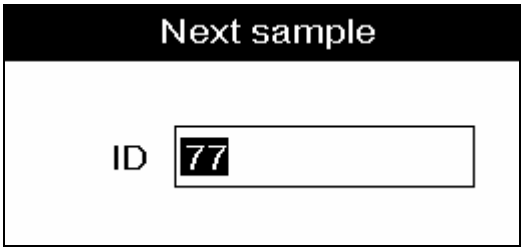


Figure 6-10 ID window

ENTER the sample ID into the ID box and press [ENTER] to save the changes and close the window. If you have the bar-code scanner installed, you can simply scan the sample ID into the analyzer.

NOTE

- **If you intend to do the background check instead of a patient sample, *ENTER* "0" into the "ID" box.**

6.6.2 Running the samples

- **Samples, controls, calibrators and waste are potentially infectious. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them in the laboratory.**

⚠ WARNING

- **The sample probe tip is sharp and may contain biohazardous materials. Exercise caution to avoid contact with the probe when working around it.**
- **Do not re-use such disposable product as collection tubes, test tubes, capillary tubes, etc.**

NOTE

- **Be sure to keep the sample probe tip away from the tube bottom, otherwise the aspiration volume may be inaccurate.**
- **When the aspiration is done, remove the sample tube only when the sample probe is out of the tube.**

1. At the "**Count**" screen, be sure the **System Status** area displays "**Ready**" and **Count Mode** area displays "**Whole**".
2. Present the mixed sample to the sample probe so that the tip is well into the tube, and press the aspirate key. The **System Status** area will display "**Running**" and the analyzer will start aspirating sample.
3. When you hear the beep and the sample probe is out of the tube, remove the sample tube. The sample probe will retract into the analyzer and the analysis progress will be displayed on the screen.
4. When the analysis is finished, the result will be displayed on the screen and the sample ID will automatically increase by 1 and the sample probe will be replaced. And if the auto print function is enabled, the analysis result will be automatically printed out.
5. Repeat the above steps on other samples.

NOTE

- **If the analyzer detects WBC/RBC clogging or bubbles during the analysis, the corresponding error messages will be displayed in the upper left corner of the screen and the results of all the related parameters will be invalidated. See Chapter 11 Troubleshooting for solutions.**
- **If the ambient temperature is outside the specified operating range, the analyzer will alarm you for abnormal ambient temperature and the analysis results may be unreliable. See Chapter 11 Troubleshooting for solutions.**

6.6.3 Special Functions

Automatic saving of analysis results

This analyzer automatically saves maximum 35,000 sample results. When the maximum number has been reached, the newest result will overwrite the oldest.

Parameter flags

■ If the analysis result is followed by an "**H**" or "**L**"**,** it means the analysis result has exceeded the upper or lower limit of the reference range.

■ If you see ******* as opposed to the result, it means the result is either unreliable or out of the operating range.

■ If the WBC result is less than 0.5×10^9/L, this analyzer will not perform the differential analysis and all the related parameter values will be non-numeric (*******)**.**

NOTE

- **The result of the background check will not be flagged.**

Histogram flags

The system will flag abnormal histograms.

■ Abnormal WBC histograms will be flagged by one of the markings: R1，R2，R3，R4 and $R_{m.}$

R_1：indicates abnormality on the left side of the lymphocyte hump and possible presence of platelets coagulate, large platelet, nucleated red cell, insolvable red cell, protein, lipoid debris in sample, or electrical noise.

R_2: indicates abnormality between the lymphocyte hump and the mononuclear area and possible presence of atypical lymphocyte, original cell in the sample and increased eosinophil or increased basophil.

R_3：indicates abnormality between the mononuclear leukocyte and the neutrophilic granulocytes and possible presence of immature granulocytes, abnormal sub-population in the sample, or increased eosinophil.

R_4：indicates abnormality on the right side of the neutrophilic granulocytes hump and increased absolute number of neutrophilic granulocyte.

R_m：indicates at least two R flags.

■ Abnormal PLT histograms will be flagged by one of the markings: P_m，P_S and $P_{L.}$

P_m：indicates blur demarcation between the platelet and red blood cell area and possible presence of large platelet, platelet coagulation, small red blood cell, cell debris or fibrin.

P_S：indicates excessive small PLTs.

P_L：indicates excessive large PLTs.

NOTE

- **When the PLT value is less than 100 × 10^9 / L, a manual count by the microscope is recommended.**

Adjusting histograms manually

If you are not satisfied with the obtained histograms, you can adjust them manually, provided you have the administrator password. See **Chapter 7 Reviewing Sample Results** for details.

Screen saver

This analyzer will enter the screen saver if it has been idle at the "**Count**" screen for 10 minutes. When it happens, the sample probe will retract into the analyzer, the LCD will turn dark and the power indicator will be flickering. You can press any key to resume the display and replace the sample probe.

6.7 Running Prediluted Samples

Press [MENU] and ***SELECT*** "**Sample Mode**" (Figure 6-11) to enter the "**Sample Mode**" (Figure6-12) screen.

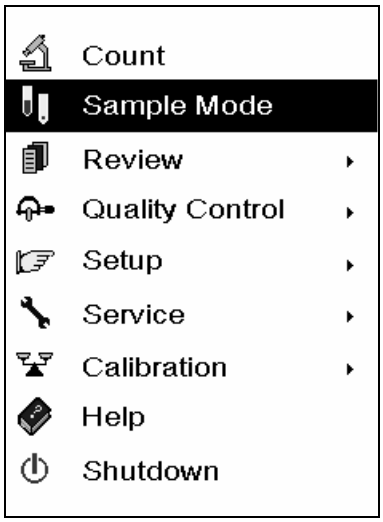


Figure 6-11 System menu

SELECT "**Predilute**" ***from the*** "**Sample Mode**" ***pull-down list***.

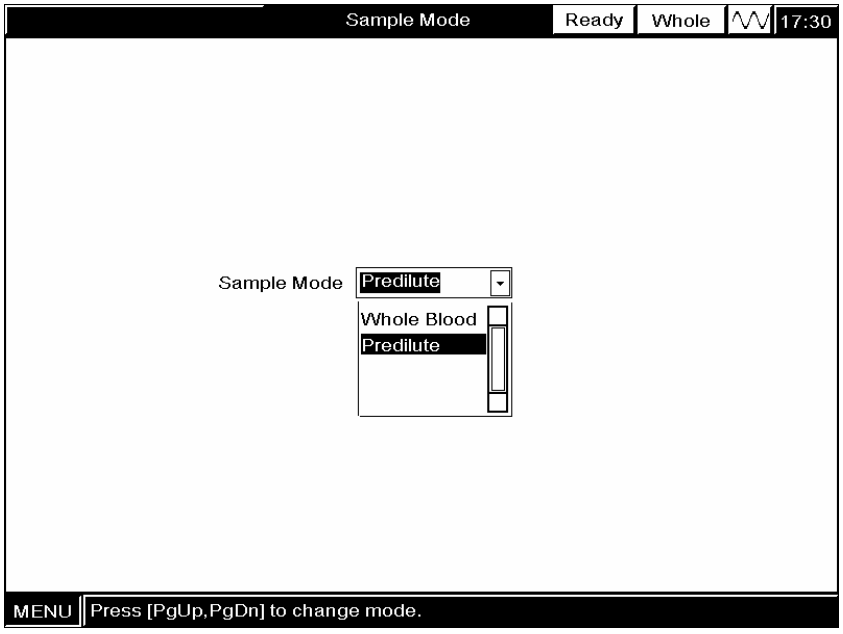


Figure6-12 Selecting Predilute mode

Press [MENU] and ***SELECT*** "**Count**" to enter the "**Count**" screen,as Figure6-13 shows.

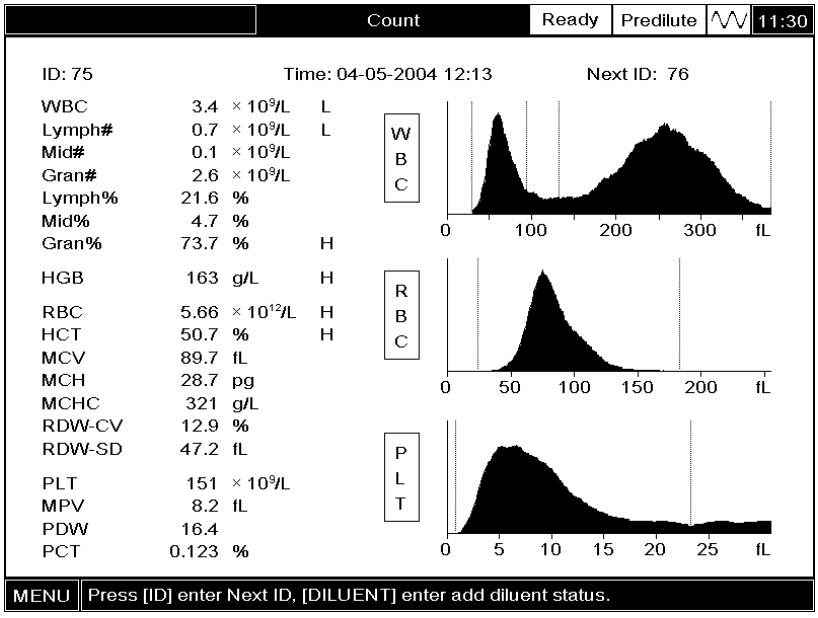


Figure6-13 "Count" screen

NOTE

- **Be sure to select a proper reference range as instructed in Chapter 5.5 before running the samples. Otherwise, the obtained results may be erroneously flagged.**

6.7.1 Entering Sample Information

You can enter the sample information one of the two ways, **ID or All Info.,** depending on the configuration of your analyzer (see **Chapter 5.13** for how to select the entering mode).

All Info. (external keyboard needed)

At the "**Count**" screen, press [ID] and an edit window will pop up, as Figure6-14 shows.

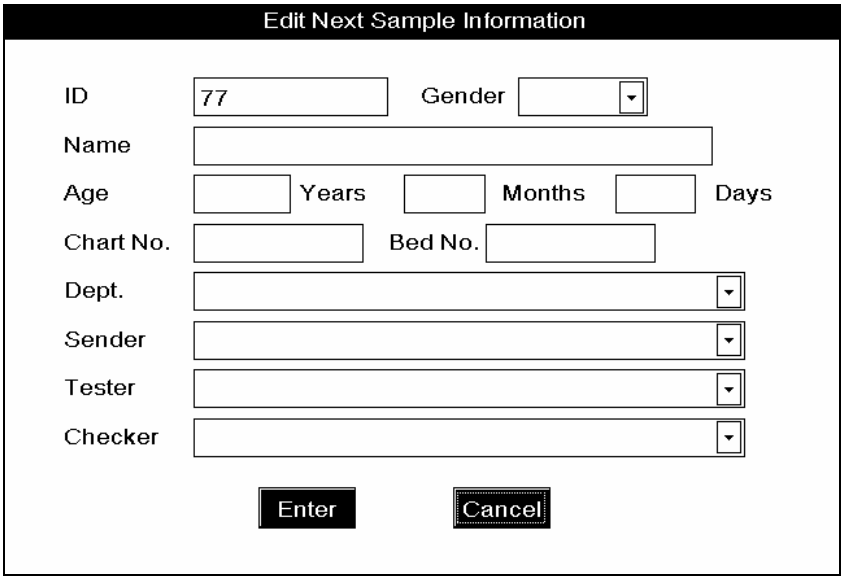


Figure6-14 Entering all sample information

- Entering sample ID

ENTER the ID number in the "**ID**" box, or if you have the bar-code scanner installed, you can simply scan the sample ID into the analyzer.

- Selecting patient gender

SELECT the desired item ***from the*** "**Gender**" ***pull-down list,*** as Figure6-15 shows. Note that you can select blank in case you are not aware of the patient gender.

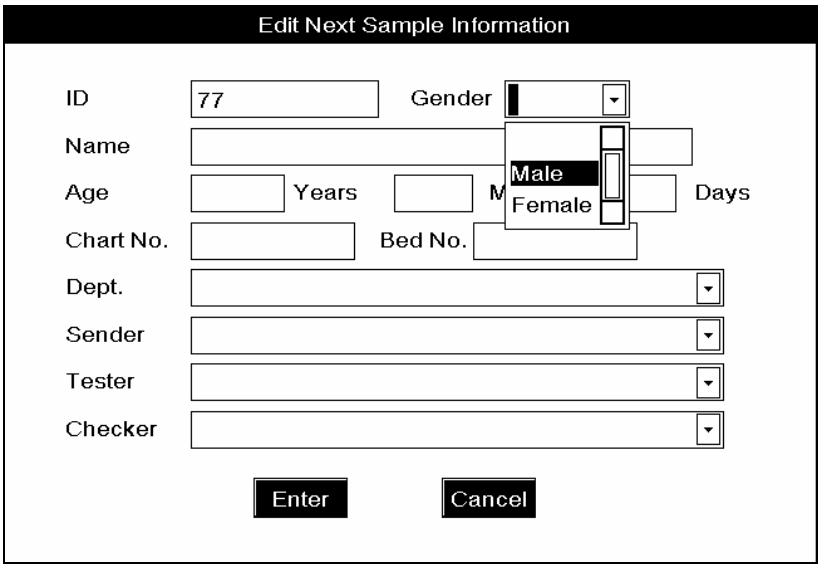


Figure6-15 How to select the patient gender

- Entering the patient name

  ENTER the patient name into the "**Name**" box.

- Entering the patient age

This analyzer provides three ways for you to enter the patient age –in years, in months and in days. The first way is designed for the adult or pediatric patients no younger than one year; the second for the infant patients one month to one year; the third for the neonatal patients no older than 28 days s. You can choose only one of the three ways to enter the patient age.

To enter the patient age in years：***ENTER*** the desired number, an integer from 0 to 200, into the "**Years**" box.
To enter the patient age in months： ***ENTER*** the desired number, an integer from 0 to 12, into the "**Months**" box.
To enter the patient age in days：***ENTER*** the desired number, an integer from 0 to 31, into the "**Days**" box.

- Entering the chart number

  ENTER the number of the patient's medical chart into the "**Chart No.**" box.

- Entering the bed number

  ENTER the number of the patient's bed into the"**Bed No.** "box.

- Entering the department name

You can either directly ***ENTER*** the name of the department, from which the sample came, into the "**Department**" box or ***SELECT*** the desired department ***from the*** "**Department**" ***pull-down list*** (if there are previously saved departments in the list, as Figure6-16 shows).

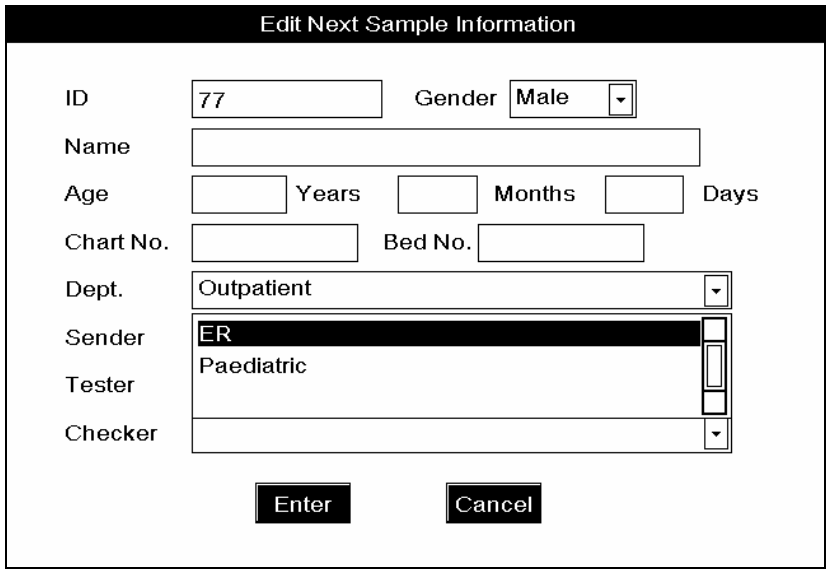


Figure6-16 How to select department name from the pull-down list

- Entering the names of the sender, tester and reviewer

To enter the name of the person who sent the sample for analysis, enter the name into the "**Sender**" box or ***SELECT*** the desired name **from the** "**Sender**" **pull-down list** (if there are previously saved names in the list, as Figure6-17 shows) ; to enter the name of the person who is to run (or has run) the sample, enter the name into the "**Tester**" box or ***SELECT*** the desired name **from the** "**Tester**" **pull-down list** (if there are previously saved names in the list) ; to enter the name of the person who is to review the sample results, enter the name into the "**Reviewer**" box, or ***SELECT*** the desired name **from the** "**Reviewer**" **pull-down list** (if there are previously saved names in the list). All the three pull-down lists are capable of saving 30 entered names.

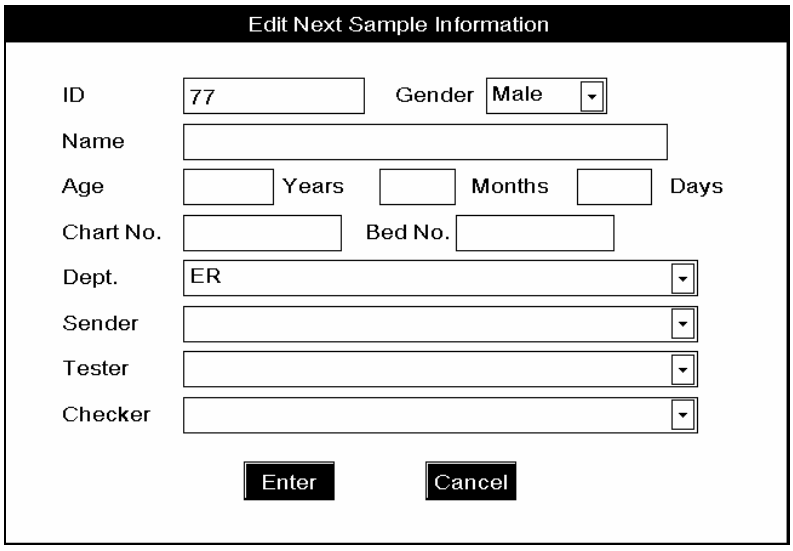


Figure6-17 Entering names of the sender, tester and reviewer

- "**Enter**" button

When you have finished entering the all the interested sample information, ***CLICK*** the "**Enter**" button to save the changes and return to the "**Count**" screen.

- "**Cancel**" button

If you do not want to save the entered information, ***CLICK*** the "**Cancel**" button to return to the "**Count**" screen without saving the changes.

ID Only

At the "**Count**" screen, press [ID] and an ID window will pop up, as Figure6-18 shows.

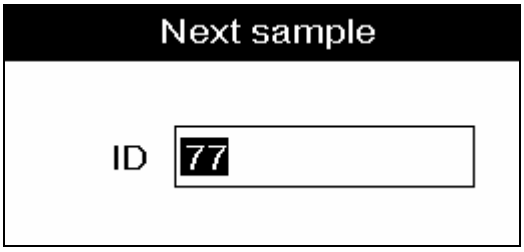


Figure6-18 ID window

ENTER the sample ID into the ID box and press [ENTER] to save the changes and close the window.

NOTE

- **If you intend to do the background check instead of a patient sample, enter "0" into the "ID" box.**

6.7.2 Running the Samples

- **Samples, controls, calibrators and waste are potentially infectious. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them in the laboratory.**

⚠ WARNING

- **The sample probe tip is sharp and may contain biohazardous materials. Exercise caution to avoid contact with the probe when working around it.**
- **Do not re-use such disposable product as collection tubes, test tubes, capillary tubes, etc.**

NOTE

- **Be sure to keep the sample probe tip away from the tube bottom, otherwise the aspiration volume may be inaccurate.**
- **When the aspiration is done, remove the sample tube only when the sample probe is out of the tube.**

1. At the "**Count**" screen, be sure the **System Status** area displays "**Ready**" and **Count Mode** area displays "**Predilute**".
2. Present the mixed sample to the sample probe so that the tip is well into the tube, and press the aspirate key. The **System Status** area will display "**Running**" and the analyzer will start aspirating sample.
3. When you hear the beep and the sample probe is out of the tube, remove the sample tube. The sample probe will retract into the analyzer and the analysis progress will be displayed on the screen.
4. When the analysis is finished, the result will be displayed on the screen and the sample ID will automatically increase by 1 and the sample probe will be replaced. And if the auto print function is enabled, the analysis result will be automatically printed out.
5. Repeat the above steps on other samples.

NOTE

- **If the analyzer detects WBC/RBC clogging or bubbles during the analysis, the corresponding error messages will be displayed in the upper left corner of the screen and the results of all the related parameters will be invalidated. See Chapter 11 Troubleshooting for solutions.**
- **If the ambient temperature is outside the specified operating range, the analyzer will alarm you for abnormal ambient temperature and the analysis results may be unreliable. See Chapter 11 Troubleshooting for solutions.**

6.7.3 Special Functions

Automatic saving of analysis results

This analyzer automatically saves maximum 35,000 sample results. When the maximum number has been reached, the newest result will overwrite the oldest.

Parameter flags

■ If the analysis result is followed by an "**H**" or "**L**"**,** it means the analysis result has exceeded the upper or lower limit of the reference range.

■ If you see ******* as opposed to the result, it means the result is either unreliable or out of the operating range.

■ If the WBC result is less than 0.5×10^9/L, this analyzer will not perform the differential analysis and all the related parameter values will be non-numeric (*******)**.**

NOTE

- **The result of the background check will not be flagged.**

Histogram flags

The system will flag abnormal histograms.

■ Abnormal WBC histograms will be flagged by one of the markings: R1，R2，R3，R4 and $R_{m.}$

R_1：indicates abnormality on the left side of the lymphocyte hump and possible presence of platelets coagulate, large platelet, nucleated red cell, insolvable red cell, protein, lipoid debris in sample, or electrical noise.

R_2: indicates abnormality between the lymphocyte hump and the mononuclear area and possible presence of atypical lymphocyte, original cell in the sample and increased eosinophil or increased basophil.

R_3：indicates abnormality between the mononuclear leukocyte and the neutrophilic granulocytes and possible presence of immature granulocytes, abnormal sub-population in the sample, or increased eosinophil.

R_4：indicates abnormality on the right side of the neutrophilic granulocytes hump and increased absolute number of neutrophilic granulocyte.

R_m：indicates at least two R flags.

■ Abnormal PLT histograms will be flagged by one of the markings: P_m，P_S and $P_{L.}$

P_m：indicates blur demarcation between the platelet and red blood cell area and possible

presence of large platelet, platelet coagulation, small red blood cell, cell debris or fibrin.

P_S：indicates excessive small PLTs.

P_L：indicates excessive large PLTs.

NOTE

- **When the PLT value is less than 100 × 10^9 / L, a manual count by the microscope is recommended.**

Adjusting histograms manually

If you are not satisfied with the obtained histograms, you can adjust them manually, provided you have the administrator password. See **Chapter 7 Reviewing Sample Results** for details.

Screen saver

This analyzer will enter the screen saver if it has been idle at the "**Count**" screen for 10 minutes. When it happens, the sample probe will retract into the analyzer, the LCD will turn dark and the power indicator will be flickering. You can press any key to resume the display and replace the sample probe.

6.8 Shutdown

Perform the "**Shutdown**"procedure to shut down the analyzer daily.

NOTE

- **To ensure stable analyzer performance and accurate analysis results, be sure to perform the "Shutdown"procedure to shut down the analyzer after it has been running continuously for 24 hours.**
- **Be sure to shut down the analyzer strictly as instructed below.**

1. Press [MENU] to enter the system menu and ***SELECT*** "**Shutdown**", as Figure 6-19 shows;

Figure 6-19 Selecting the Shutdown program

2. A message box will pop up to ask you to confirm the shutdown, as Figure 6-20shows;

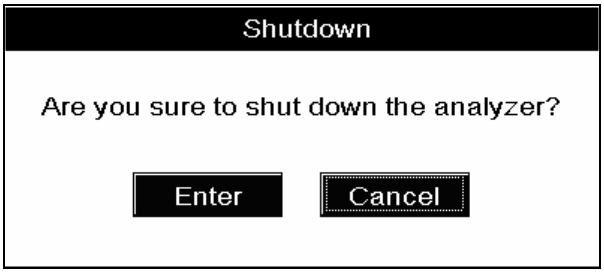


Figure 6-20 Shutdown message box

3. ***CLICK*** "***Enter***"and a window will pop up to instruct you how to shut down the analyzer, as Figure6-21shows;

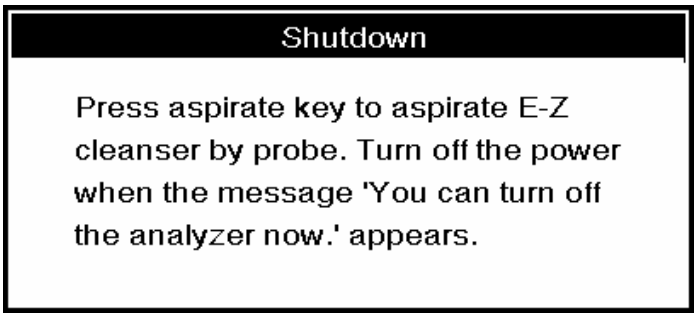

Shutdown
Press aspirate key to aspirate E-Z cleanser by probe. Turn off the power when the message 'You can turn off the analyzer now.' appears.

Figure6-21 Shutdown window

⚠ WARNING

- **The sample probe tip is sharp and may contain biohazardous materials. Exercise caution to avoid contact with the probe when working around it.**
- **The reagents are irritating to eyes, skin and diaphragm. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them in the laboratory.**

4. Present the E-Z cleanser to the sample probe and press the aspirate key. The analyzer will aspirate the E-Z cleanser and automatically clean the fluidic lines and the baths. The cleaning progress will be displayed on the screen, as Figure 6-22 shows;

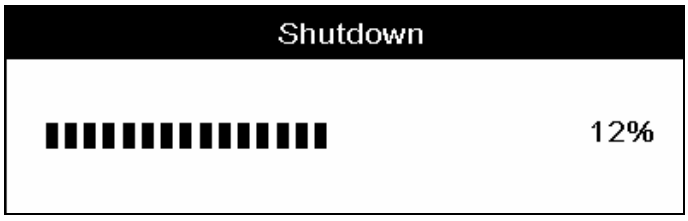


Figure 6-22 Shutdown progress bar

5. When the cleaning is finished, place the switch at the back of the analyzer to OFF (O) to turn off the analyzer;
6. Empty the waste container.

- **Samples, controls, calibrators and waste are potentially infectious. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them in the laboratory.**

⚠ WARNING

- **Be sure to dispose of reagents, waste, samples, consumables, etc. according to government regulations.**

7 Reviewing Sample Results

7.1 Introduction

The analyzer automatically saves analysis results. Totally 35,000 results can be saved. You can either browse all the saved sample results in general (see “Browsing All Sample Results”) or search for the results of a particular sample or samples (see “Searching for Interested Sample Results”).

7.2 Browsing All Sample Results

To browse all the saved sample results, you can choose either of the following modes:

- The "**Sample Table Review**" mode. In this mode, the sample results are presented in a columnar fashion without histograms (namely you can only see the parameter values). One screen displays maximum 6 sample results.
- The "**Sample Histogram Review**" mode. In this mode, you can review both parameter values and histograms of the saved sample results. One screen displays one sample result.

7.2.1 Browsing in the "Sample Table Review" mode

Entering the "Sample Table Review" screen

Press [MENU] to enter the system menu. ***SELECT*** "**Review→ Sample Review→ Sample Table Review**" (Figure7-1), to enter the "**Sample Table Review**" screen (Figure7-2).

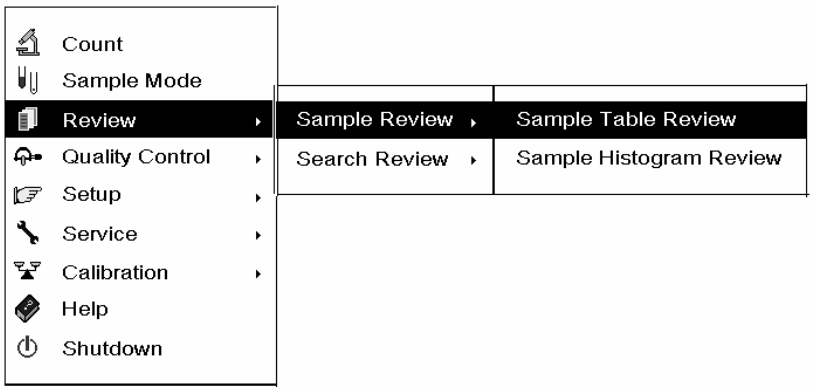
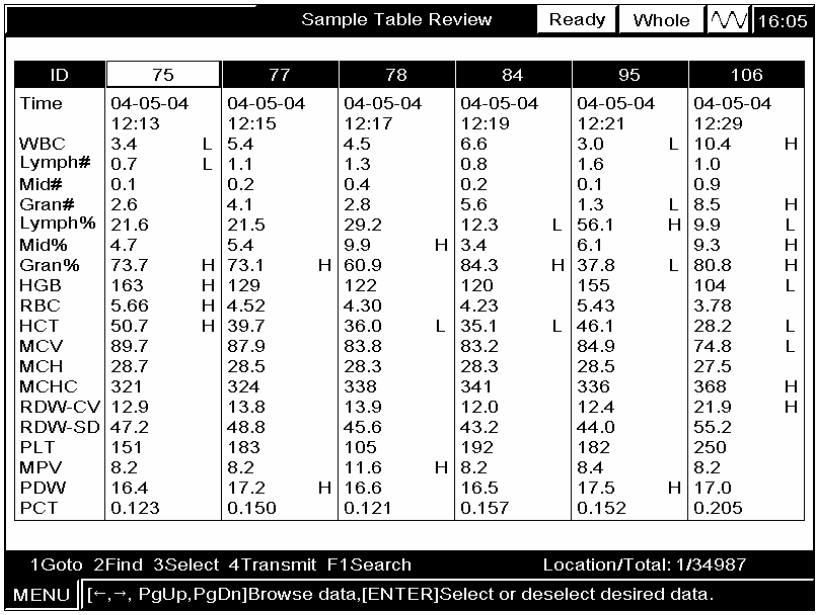


Figure7-1 System menu

The sample results are sequentially displayed on the screen, the earliest on the utmost left. The "**Location/Total**" displayed in the lower right corner of the screen indicates the location of the current sample result (the one whose "**ID**" is backlit) and the total number of the saved sample results.



ID	75	77	78	84	95	106
Time	04-05-04 12:13	04-05-04 12:15	04-05-04 12:17	04-05-04 12:19	04-05-04 12:21	04-05-04 12:29
WBC	3.4 L	5.4	4.5	6.6	3.0 L	10.4 H
Lymph#	0.7 L	1.1	1.3	0.8	1.6	1.0
Mid#	0.1	0.2	0.4	0.2	0.1	0.9
Gran#	2.6	4.1	2.8	5.6	1.3 L	8.5 H
Lymph%	21.6	21.5	29.2	12.3 L	56.1 H	9.9 L
Mid%	4.7	5.4	9.9 H	3.4	6.1	9.3 H
Gran%	73.7 H	73.1 H	60.9	84.3 H	37.8 L	80.8 H
HGB	163 H	129	122	120	155	104 L
RBC	5.66 H	4.52	4.30	4.23	5.43	3.78
HCT	50.7 H	39.7	36.0 L	35.1 L	46.1	28.2 L
MCV	89.7	87.9	83.8	83.2	84.9	74.8 L
MCH	28.7	28.5	28.3	28.3	28.5	27.5
MCHC	321	324	338	341	336	368 H
RDW-CV	12.9	13.8	13.9	12.0	12.4	21.9 H
RDW-SD	47.2	48.8	45.6	43.2	44.0	55.2
PLT	151	183	105	192	182	250
MPV	8.2	8.2	11.6 H	8.2	8.4	8.2
PDW	16.4	17.2 H	16.6	16.5	17.5 H	17.0
PCT	0.123	0.150	0.121	0.157	0.152	0.205

Figure7-2 "Sample Table"screen

Browsing sample results

Press [←] or [→] to browse the preceding or following sample result; press [PgUp] or [PgDn] to browse the preceding or following screen.

Switching to the "Sample Histogram Review" mode

If you are interested in reviewing the histograms of the current sample result, press [6] to switch to the "**Sample Histogram Review**" mode. To switch back to the "**Sample Table Review**" mode, press [6] again.

Jumping to a sample result with known location

Press [1] and a "**Goto**" window will pop up, as Figure7-3 shows.

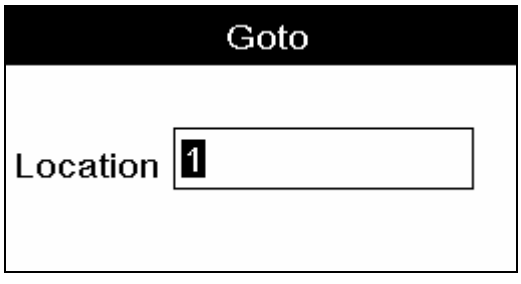


Figure7-3 "Goto" window

ENTER the location into the "**Location**" box and press [ENTER] to jump to the desired sample result.

Jumping to a sample result with known sample ID

Press [2] and a "**Find**" window will pop up, as Figure7-4 shows.

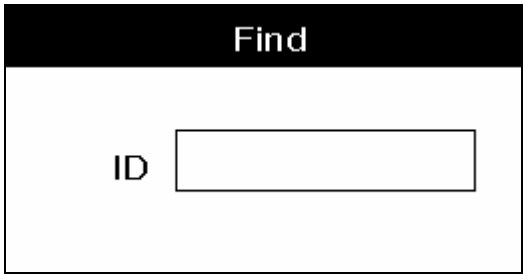


Figure7-4 "Find"window

ENTER the sample ID into the "**ID**" box and press [↑] to search backward or [↓] to search forward. If the desired sample result is found, the analyzer will jump to it; if not, a message box will pop up, as Figure7-5 shows. Press [ENTER] to close the message box.

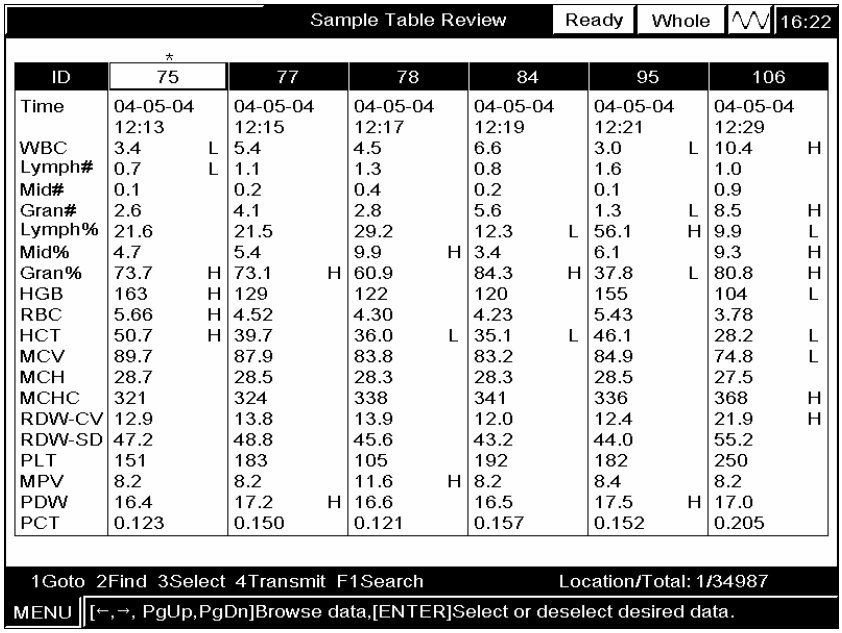
Figure7-5 A "Result"message box

Selecting/deselecting sample results

You can select certain interested samples for transmission or printing.

- Selecting/deselecting a sample result

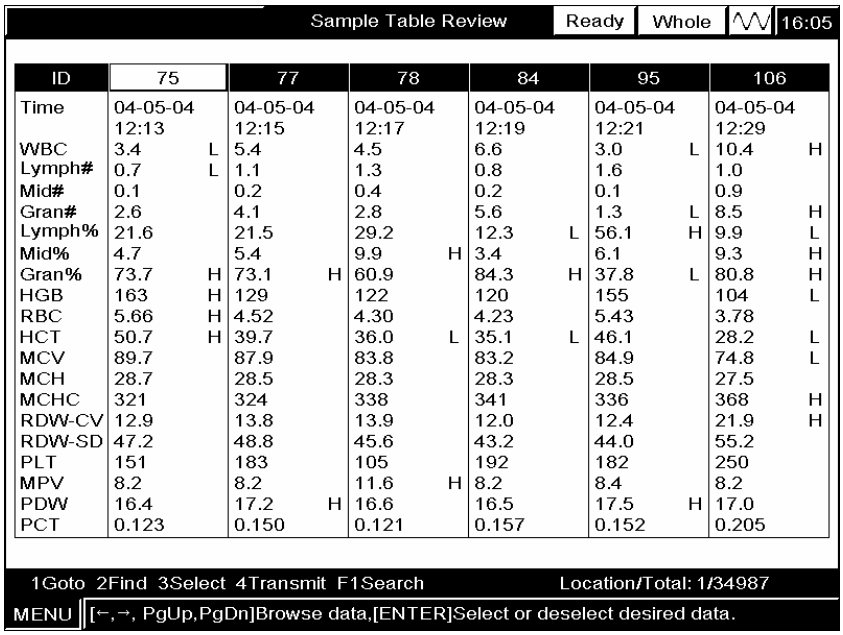
Press [←] or [→] to move the cursor to the interested sample result and press [ENTER] to select it. The selected sample result will be marked with a "*", as sample "75" in Figure7-6 shows.



ID	* 75	77	78	84	95	106
Time	04-05-04 12:13	04-05-04 12:15	04-05-04 12:17	04-05-04 12:19	04-05-04 12:21	04-05-04 12:29
WBC	3.4 L	5.4	4.5	6.6	3.0 L	10.4 H
Lymph#	0.7 L	1.1	1.3	0.8	1.6	1.0
Mid#	0.1	0.2	0.4	0.2	0.1	0.9
Gran#	2.6	4.1	2.8	5.6	1.3 L	8.5 H
Lymph%	21.6	21.5	29.2	12.3 L	56.1 H	9.9 L
Mid%	4.7	5.4	9.9 H	3.4	6.1	9.3 H
Gran%	73.7 H	73.1 H	60.9	84.3 H	37.8 L	80.8 H
HGB	163 H	129	122	120	155	104 L
RBC	5.66 H	4.52	4.30	4.23	5.43	3.78
HCT	50.7 H	39.7	36.0 L	35.1 L	46.1	28.2 L
MCV	89.7	87.9	83.8	83.2	84.9	74.8 L
MCH	28.7	28.5	28.3	28.3	28.5	27.5
MCHC	321	324	338	341	336	368 H
RDW-CV	12.9	13.8	13.9	12.0	12.4	21.9 H
RDW-SD	47.2	48.8	45.6	43.2	44.0	55.2
PLT	151	183	105	192	182	250
MPV	8.2	8.2	11.6 H	8.2	8.4	8.2
PDW	16.4	17.2 H	16.6	16.5	17.5 H	17.0
PCT	0.123	0.150	0.121	0.157	0.152	0.205

Figure7-6 Selecting a sample result

Press [ENTER] again to deselect the sample result. Once the sample is deselected, the "*" will disappear, as sample "**75**" in Figure7-7 shows.



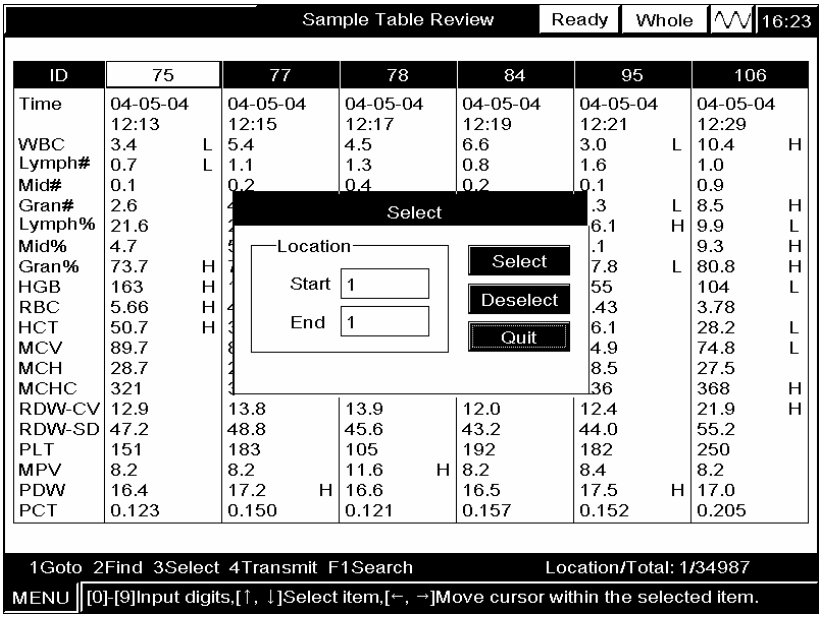
ID	75	77	78	84	95	106
Time	04-05-04 12:13	04-05-04 12:15	04-05-04 12:17	04-05-04 12:19	04-05-04 12:21	04-05-04 12:29
WBC	3.4 L	5.4	4.5	6.6	3.0 L	10.4 H
Lymph#	0.7 L	1.1	1.3	0.8	1.6	1.0
Mid#	0.1	0.2	0.4	0.2	0.1	0.9
Gran#	2.6	4.1	2.8	5.6	1.3 L	8.5 H
Lymph%	21.6	21.5	29.2	12.3 L	56.1 H	9.9 L
Mid%	4.7	5.4	9.9 H	3.4	6.1	9.3 H
Gran%	73.7 H	73.1 H	60.9	84.3 H	37.8 L	80.8 H
HGB	163 H	129	122	120	155	104 L
RBC	5.66 H	4.52	4.30	4.23	5.43	3.78
HCT	50.7 H	39.7	36.0 L	35.1 L	46.1	28.2 L
MCV	89.7	87.9	83.8	83.2	84.9	74.8 L
MCH	28.7	28.5	28.3	28.3	28.5	27.5
MCHC	321	324	338	341	336	368 H
RDW-CV	12.9	13.8	13.9	12.0	12.4	21.9 H
RDW-SD	47.2	48.8	45.6	43.2	44.0	55.2
PLT	151	183	105	192	182	250
MPV	8.2	8.2	11.6 H	8.2	8.4	8.2
PDW	16.4	17.2 H	16.6	16.5	17.5 H	17.0
PCT	0.123	0.150	0.121	0.157	0.152	0.205

Figure7-7 Deselecting a sample result

■ Selecting/deselecting multiple sample results

Example1：To select the sample results of locations 1 – 5 (sample ID:75, 77, 78, 84, 95 in Figure7-8), follow the procedure below to do so:

1. Press[3] to enter the "**Select**" window, as Figure7-8 shows;



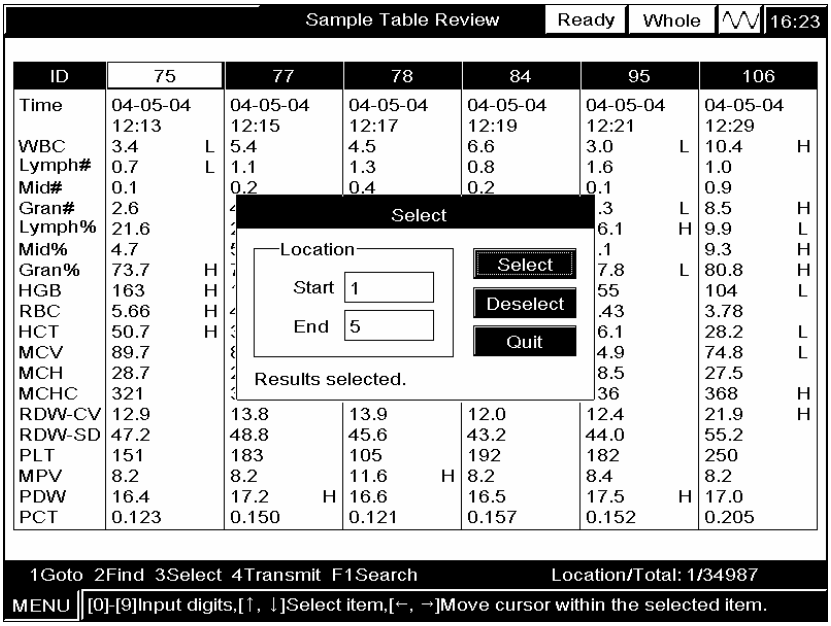
ID	75	77	78	84	95	106
Time	04-05-04 12:13	04-05-04 12:15	04-05-04 12:17	04-05-04 12:19	04-05-04 12:21	04-05-04 12:29
WBC	3.4 L	5.4	4.5	6.6	3.0 L	10.4 H
Lymph#	0.7 L	1.1	1.3	0.8	1.6	1.0
Mid#	0.1	0.2	0.4	0.2	0.1	0.9
Gran#	2.6				.3 L	8.5 H
Lymph%	21.6				6.1 H	9.9 L
Mid%	4.7				.1	9.3 H
Gran%	73.7 H				7.8 L	80.8 H
HGB	163 H				55	104 L
RBC	5.66 H				.43	3.78
HCT	50.7 H				6.1	28.2 L
MCV	89.7				4.9	74.8 L
MCH	28.7				8.5	27.5
MCHC	321				36	368 H
RDW-CV	12.9	13.8	13.9	12.0	12.4	21.9 H
RDW-SD	47.2	48.8	45.6	43.2	44.0	55.2
PLT	151	183	105	192	182	250
MPV	8.2	8.2	11.6 H	8.2	8.4	8.2
PDW	16.4	17.2 H	16.6	16.5	17.5 H	17.0
PCT	0.123	0.150	0.121	0.157	0.152	0.205

Figure7-8 Entering the "Select" window

2. ***ENTER*** the start position ("**1**") into the "**Start**" box;

3. ***ENTER*** the start position ("**5**") into the "**End**" box;

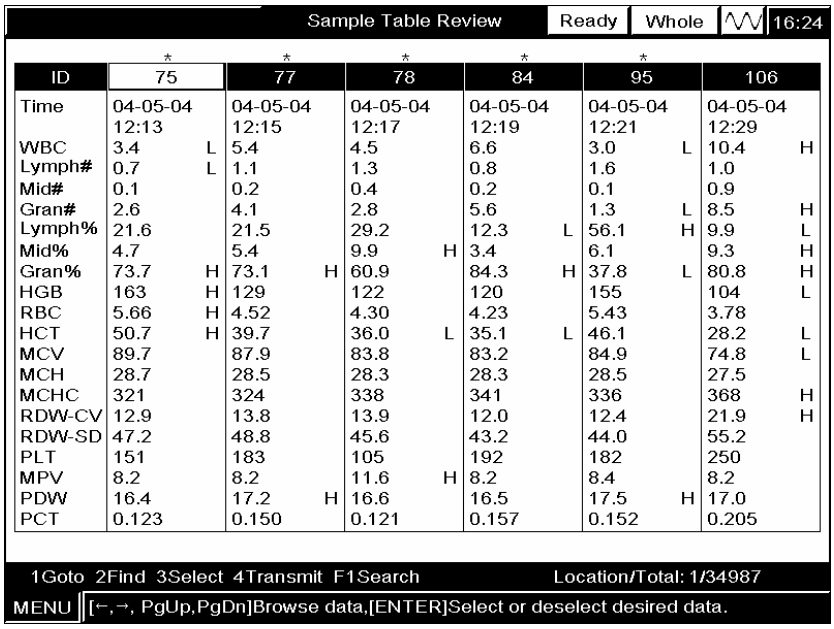
4. ***CLICK*** "**Select**" and the lower left corner of the "**Select**" window will display "**Results selected**", as Figure7-9 shows;



ID	75	77	78	84	95	106
Time	04-05-04 12:13	04-05-04 12:15	04-05-04 12:17	04-05-04 12:19	04-05-04 12:21	04-05-04 12:29
WBC	3.4 L	5.4	4.5	6.6	3.0 L	10.4 H
Lymph#	0.7 L	1.1	1.3	0.8	1.6	1.0
Mid#	0.1	0.2	0.4	0.2	0.1	0.9
Gran#	2.6				.3 L	8.5 H
Lymph%	21.6				6.1 H	9.9 L
Mid%	4.7				.1	9.3 H
Gran%	73.7 H				7.8 L	80.8 H
HGB	163 H				55	104 L
RBC	5.66 H				.43	3.78
HCT	50.7 H				6.1	28.2 L
MCV	89.7				4.9	74.8 L
MCH	28.7				8.5	27.5
MCHC	321				36	368 H
RDW-CV	12.9	13.8	13.9	12.0	12.4	21.9 H
RDW-SD	47.2	48.8	45.6	43.2	44.0	55.2
PLT	151	183	105	192	182	250
MPV	8.2	8.2	11.6 H	8.2	8.4	8.2
PDW	16.4	17.2 H	16.6	16.5	17.5 H	17.0
PCT	0.123	0.150	0.121	0.157	0.152	0.205

Figure7-9 Selecting sample results of locations 1- 5

5. ***CLICK*** "**Quit**" to return to the "**Sample Table Review**" screen. The selected sample results will be marked with "*", as Figure7-10 shows.



ID	* 75		* 77		* 78		* 84		* 95		106	
Time	04-05-04 12:13		04-05-04 12:15		04-05-04 12:17		04-05-04 12:19		04-05-04 12:21		04-05-04 12:29	
WBC	3.4	L	5.4		4.5		6.6		3.0	L	10.4	H
Lymph#	0.7	L	1.1		1.3		0.8		1.6		1.0	
Mid#	0.1		0.2		0.4		0.2		0.1		0.9	
Gran#	2.6		4.1		2.8		5.6		1.3	L	8.5	H
Lymph%	21.6		21.5		29.2		12.3	L	56.1	H	9.9	L
Mid%	4.7		5.4		9.9	H	3.4		6.1		9.3	H
Gran%	73.7	H	73.1	H	60.9		84.3	H	37.8	L	80.8	H
HGB	163	H	129		122		120		155		104	L
RBC	5.66	H	4.52		4.30		4.23		5.43		3.78	
HCT	50.7	H	39.7		36.0	L	35.1	L	46.1		28.2	L
MCV	89.7		87.9		83.8		83.2		84.9		74.8	L
MCH	28.7		28.5		28.3		28.3		28.5		27.5	
MCHC	321		324		338		341		336		368	H
RDW-CV	12.9		13.8		13.9		12.0		12.4		21.9	H
RDW-SD	47.2		48.8		45.6		43.2		44.0		55.2	
PLT	151		183		105		192		182		250	
MPV	8.2		8.2		11.6	H	8.2		8.4		8.2	
PDW	16.4		17.2	H	16.6		16.5		17.5	H	17.0	
PCT	0.123		0.150		0.121		0.157		0.152		0.205	

Figure7-10 Reviewing the selected results

Example2：To deselect the sample results of locations 1 – 5 (sample ID: 75, 77, 78, 84, 95 in Figure7-10), follow the procedure below to do so:

1. Enter the start and end positions as instructed in steps 1 – 3 of Example1;
2. ***CLICK*** "**Deselect**" and the lower left corner of the "**Select**" window will display "**Results deselected**", as Figure7-11 shows;

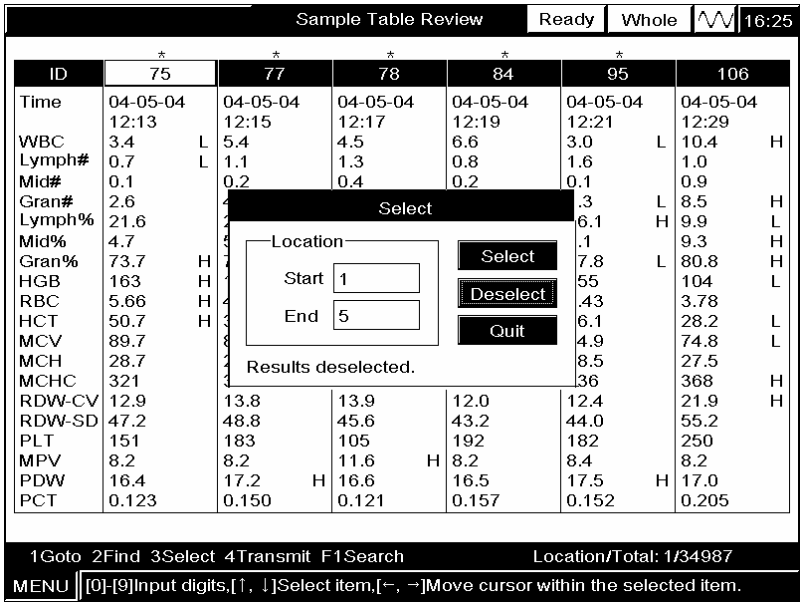
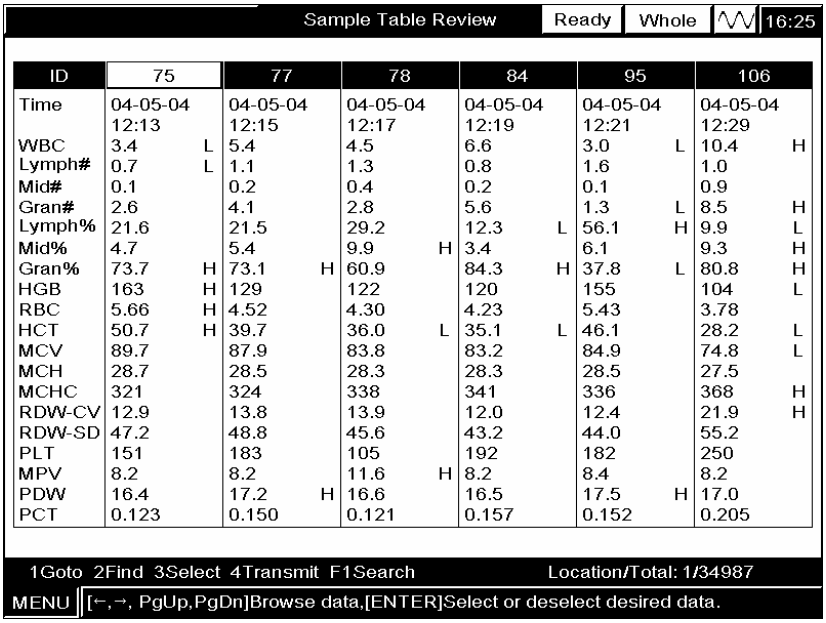


Figure7-11 Deselecting the sample results of locations 1 – 5

3. ***CLICK*** "**Quit**" to return to the "**Sample Table**" screen. The "*" above those sample results

will disappear, as Figure7-12 shows.

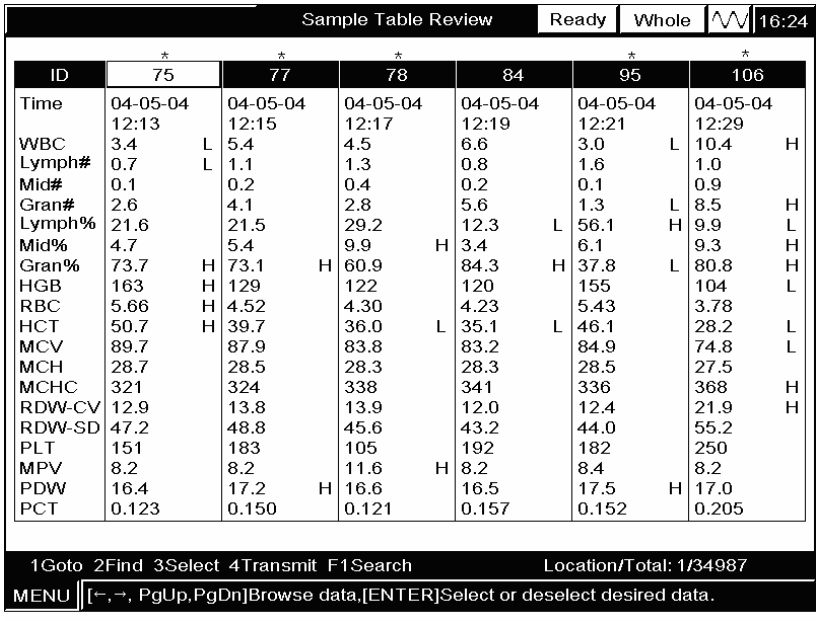


ID	75	77	78	84	95	106
Time	04-05-04 12:13	04-05-04 12:15	04-05-04 12:17	04-05-04 12:19	04-05-04 12:21	04-05-04 12:29
WBC	3.4 L	5.4	4.5	6.6	3.0 L	10.4 H
Lymph#	0.7 L	1.1	1.3	0.8	1.6	1.0
Mid#	0.1	0.2	0.4	0.2	0.1	0.9
Gran#	2.6	4.1	2.8	5.6	1.3 L	8.5 H
Lymph%	21.6	21.5	29.2	12.3 L	56.1 H	9.9 L
Mid%	4.7	5.4	9.9 H	3.4	6.1	9.3 H
Gran%	73.7 H	73.1 H	60.9	84.3 H	37.8 L	80.8 H
HGB	163 H	129	122	120	155	104 L
RBC	5.66 H	4.52	4.30	4.23	5.43	3.78
HCT	50.7 H	39.7	36.0 L	35.1 L	46.1	28.2 L
MCV	89.7	87.9	83.8	83.2	84.9	74.8 L
MCH	28.7	28.5	28.3	28.3	28.5	27.5
MCHC	321	324	338	341	336	368 H
RDW-CV	12.9	13.8	13.9	12.0	12.4	21.9 H
RDW-SD	47.2	48.8	45.6	43.2	44.0	55.2
PLT	151	183	105	192	182	250
MPV	8.2	8.2	11.6 H	8.2	8.4	8.2
PDW	16.4	17.2 H	16.6	16.5	17.5 H	17.0
PCT	0.123	0.150	0.121	0.157	0.152	0.205

Figure7-12 Reviewing the deselected results

Example3: To select the sample results of locations 1 to 5 and 7 to 8, follow the procedure below to do so:

1. Select the sample results of locations 1 to 3 as instructed in steps 1 to 5 of Example1;
2. Select the sample results of locations 5 to 6 as instructed in steps 1 to 5 of Example1;
3. ***CLICK*** "**Quit**" to return to the "**Sample Table Review**" screen. The selected sample results will be marked with "*", as Figure7-13 shows.



	*	*	*		*	*
ID	75	77	78	84	95	106
Time	04-05-04 12:13	04-05-04 12:15	04-05-04 12:17	04-05-04 12:19	04-05-04 12:21	04-05-04 12:29
WBC	3.4 L	5.4	4.5	6.6	3.0 L	10.4 H
Lymph#	0.7 L	1.1	1.3	0.8	1.6	1.0
Mid#	0.1	0.2	0.4	0.2	0.1	0.9
Gran#	2.6	4.1	2.8	5.6	1.3 L	8.5 H
Lymph%	21.6	21.5	29.2	12.3 L	56.1 H	9.9 L
Mid%	4.7	5.4	9.9 H	3.4	6.1	9.3 H
Gran%	73.7 H	73.1 H	60.9	84.3 H	37.8 L	80.8 H
HGB	163 H	129	122	120	155	104 L
RBC	5.66 H	4.52	4.30	4.23	5.43	3.78
HCT	50.7 H	39.7	36.0 L	35.1 L	46.1	28.2 L
MCV	89.7	87.9	83.8	83.2	84.9	74.8 L
MCH	28.7	28.5	28.3	28.3	28.5	27.5
MCHC	321	324	338	341	336	368 H
RDW-CV	12.9	13.8	13.9	12.0	12.4	21.9 H
RDW-SD	47.2	48.8	45.6	43.2	44.0	55.2
PLT	151	183	105	192	182	250
MPV	8.2	8.2	11.6 H	8.2	8.4	8.2
PDW	16.4	17.2 H	16.6	16.5	17.5 H	17.0
PCT	0.123	0.150	0.121	0.157	0.152	0.205

Figure7-13 Reviewing the selected results

Example4：To deselect the sample results of locations 1 to 5 and 7 to 8, follow the procedure below to do so:

1. Deselect the sample results of locations 1 to 3 as instructed in steps 1 to 3 of Example2;
2. Deselect the sample results of locations 5 to 6 as instructed in steps 1 to 3 of Example2;
3. ***CLICK*** "**Quit**" to return to the "**Sample Table Review**" screen. The "*" above those sample results will disappear, as Figure7-14 shows.

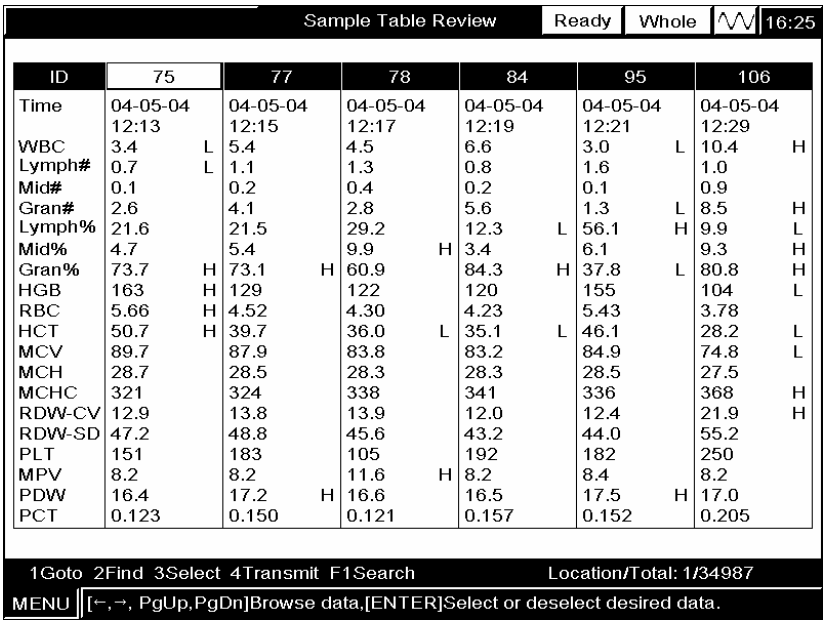


Figure7-14 Reviewing the deselected results

Transmitting sample results to a host

You can transmit the selected or all sample results to an external computer (a host). Press [4] to enter the "**Transmission**" window, as Figure7-15 shows.

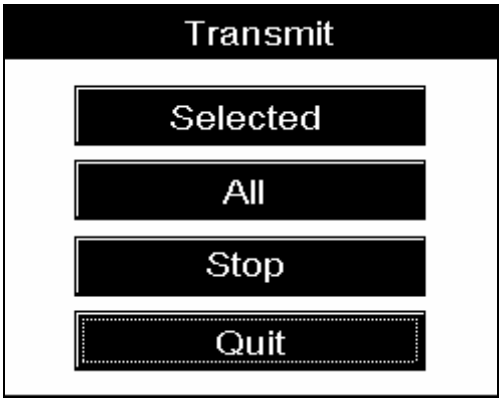


Figure7-15 "Transmission" window

To transmit the selected sample results to a host, ***CLICK*** "**Selected**"； to transmit all the sample results, ***CLICK*** "**All**"； to stop a transmission, ***CLICK*** "**Stop**"; to return to the "**Sample Table Review**"screen, ***CLICK*** "**Quit**".

Deleting sample results (if configured and administrator passwored entered)

- Deleting some sample results

Select the sample results you want to delete and press [DEL]. A message box will pop up to confirm the deletion, as Figure7-16 shows. ***CLICK*** "**Enter**" to delete the selected results; ***CLICK*** "**Cancel**" to abort the deletion.

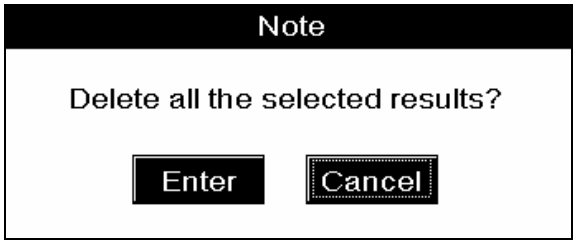


Figure7-16 A message box to confirm the deletion

- Deleting all sample results

Press [5] and a message box will pop up to ask you to confirm the deletion, as Figure7-17 shows.

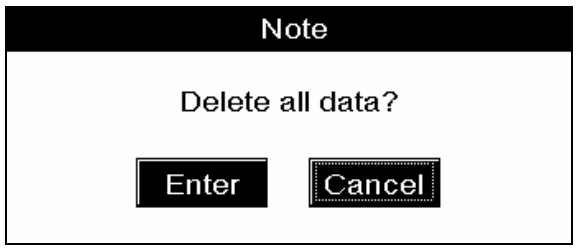


Figure7-17 A "Delete All" message box

CLICK "**Enter**" to delete all the sample results; ***CLICK*** "**Cancel**" to abort the deletion.

Printing sample results

Select the sample results you want to print and press [PRINT]. A message box will pop up to ask you to confirm the printing, as Figure7-18 shows. ***CLICK*** "**Enter**" to print out all the selected results; ***CLICK*** "**Cancel**" to abort the printing.

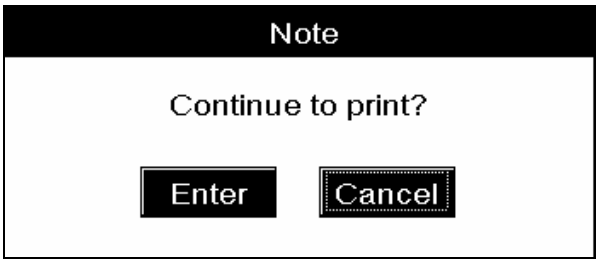


Figure7-18 A Print message box

Calculating reproducibility

This analyzer provides three reproducibility indices Mean,SD（Standard Deviation） and CV%（Coefficient of Variation）.

$$\text{Mean} = \frac{\sum_{i=1}^{n} X_i}{n}$$

$$SD = \sqrt{\frac{\sum (X_i - \text{Mean})^2}{n-1}}$$

$$CV\% = \frac{SD}{\text{Mean}} \times 100$$

Where n represents how many sample results are selected and X_i is the result of the i^{th} analysis.

To check the reproducibility of the selected sample results, select at least three sample results and press [7] to view the reproducibility. If any selected result contains invalid parameter value (s), the reproducibility indices of that parameter(s) will also be non-numeric (***).

To print out the displayed indices, press [PRIINT]. To exit the “**Reproducibility**” screen, press [MENU] to exit the “**Reproducibility**”screen.

7.2.2 Browsing in the “Sample Histogram Review” Mode

Entering the “Sample Histogram Review” screen

Press [MENU] to enter the system menu.

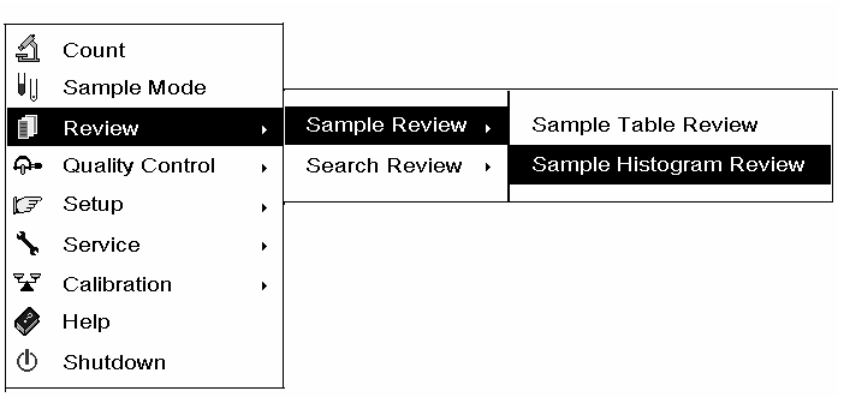


Figure7-19 System menu

SELECT "**Review → Sample Review → Sample Histogram Review**" (Figure7-19) to enter the "**Sample Histogram Review**" screen (Figure7-20). The sample information will be displayed at the top of the screen, followed by the parameter values and histograms. The "**Location/Total**" displayed in the upper right corner of the screen indicates the location of the current sample result and the total number of the saved sample results.

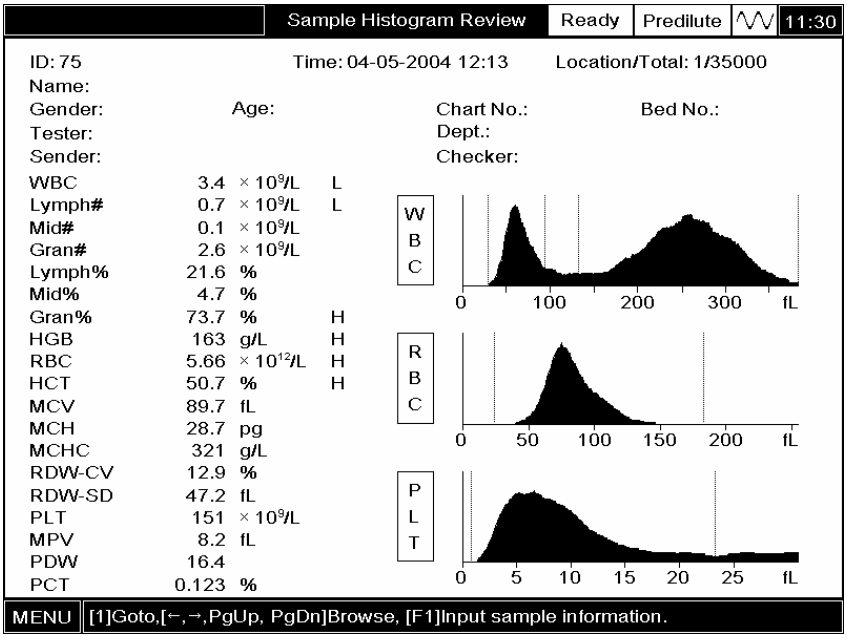


Figure7-20 "Sample Histogram Review" screen

Browsing sample results

Press [←] or [→] to browse the preceding or following sample result; press [PgUp] or [PgDn] to jump 6 locations (e.g. from location 1 to location 7).

Switching to the "Sample Table Review" mode

To switch to the "**Sample Table Review**" mode, press [6]; to switch back to the "**Sample**

Histogram Review" mode, press [6] again.

Jumping to a sample result with known location

Press [1] and a "**Goto**" window will pop up, as Figure7-21 shows.

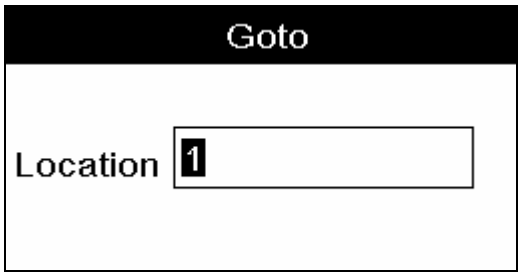


Figure7-21 "**Goto**" **window**

ENTER the location into the "**Location**" box and press [ENTER] to jump to the desired sample result.

Editing sample information

Press [F1] to edit the sample information, Figure7-22 shows.

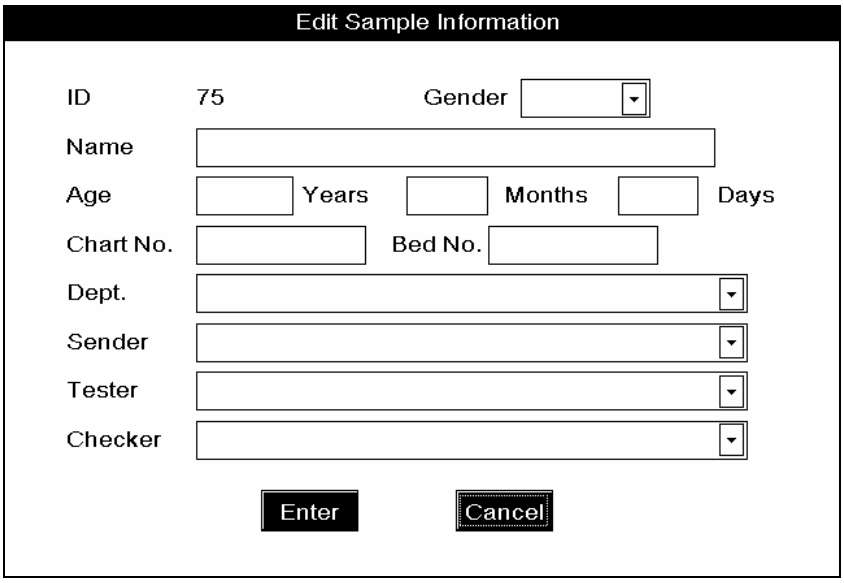


Figure7-22 Editing sample information

- ID

You cannot edit the sample ID of an analyzed sample.

- Selecting patient gender

SELECT the desired item ***from the*** "**Gender**" ***pull-down list.*** Note that you can select blank in case you are not aware of the patient gender.

- Entering the patient name

ENTER the patient name into the "**Name**" box.

- Entering the patient age

This analyzer provides three ways for you to enter the patient age – in years, in months and in days. The first way is designed for the adult or pediatric patients no younger than one year; the second for the infant patients one month to one year; the third for the neonatal patients younger than one month. You can choose only one of the three ways to enter the patient age.

To enter the patient age in years：***ENTER*** the desired number, an integer from 0 to 200, into the "**Years**" box.
To enter the patient age in months：***ENTER*** the desired number, an integer from 0 to 12, into the "**Months**" box.
To enter the patient age in days：***ENTER*** the desired number, an integer from 0 to 31, into the "**Days**" box.

- Entering the chart number

ENTER the number of the patient's medical chart into the "***Chart No.***" box.

- Entering the bed number

ENTER the number of the patient's bed into the "**Bed No.**" box.

- Entering the department name

You can either directly ***ENTER*** the name of the department, from which the sample came, into the "**Department**" box or ***SELECT*** the desired department **from the** "**Department**" **pull-down list** (if there are previously saved departments in the list.

- Entering the names of the sender, tester and reviewer

To enter the name of the person who sent the sample for analysis, ***ENTER*** the name into the "**Sender**" box or ***SELECT*** the desired name **from the** "**Sender**" **pull-down list** (if there are previously saved names in the list）; to enter the name of the person who ran the sample, ***ENTER*** the name into the "**Tester**" box or ***SELECT*** the desired name **from the** "**Tester**" **pull-down list** (if there are previously saved names in the list）; to enter the name of the person who reviewed the sample results, ***ENTER*** the name into the "**Reviewer**" box, or ***SELECT*** the desired name **from the** "**Reviewer**" **pull-down list** (if there are previously saved names in the list）. All the three pull-down lists are capable of saving 30 entered names.

- "**Enter**" button

When you have finished entering the all the interested sample information, ***CLICK*** the "**Enter**" button (or press [F4] of the external keyboard) to save the changes and return to the "**Sample Histogram Review**" screen.

- "**Cancel**" button

If you do not want to save the entered information, ***CLICK*** the "**Cancel**" button to return to the "**Sample Histogram Review**" screen without saving the changes.

Adjusting histograms

If you are not satisfied with the obtained histograms, you can adjust them manually, provided you have the administrator password.

The first three discriminators of the WBC histogram are adjustable. Note that if the WBC result is less than 0.5 or non-numeric (***), the WBC histogram is not adjustable. The first two discriminators of the RBC histogram are adjustable. Note that if the RBC result is less than 0.2 or non-numeric (***), the RBC histogram is not adjustable. The first two discriminators of the PLT histogram are adjustable. Note that if the PLT result is less than 10 or non-numeric (***), the PLT histogram is not adjustable.

Example 5：To move the third discriminator of the following WBC histogram to 100fL, follow the procedure below to do so.

1. Press [ENTER] and the discriminator will become adjustable. See Figure7-23;

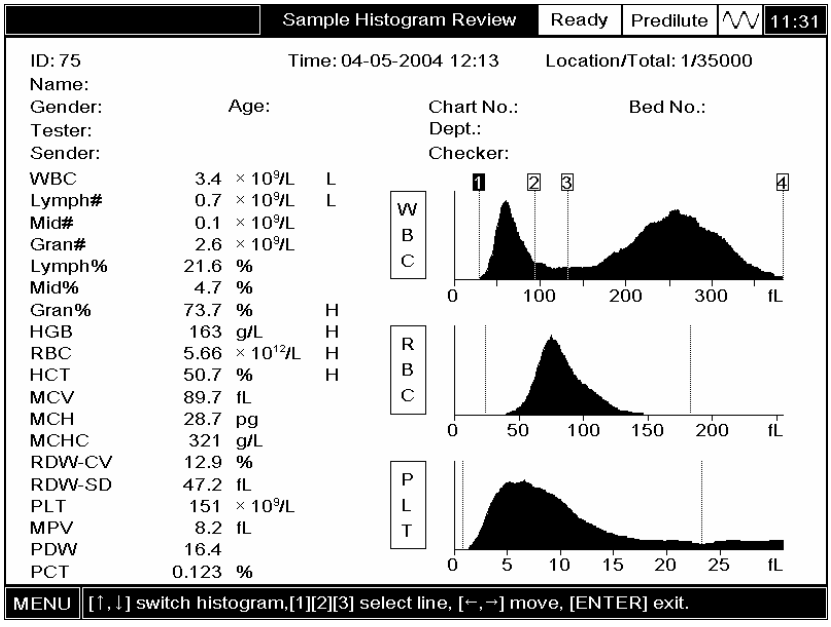


Figure7-23 WBC histogram with adjustable discriminators

2. Press [↑] or [↓] to select the WBC histogram;

3. Press [3] to select the third discriminator, as Figure7-24;

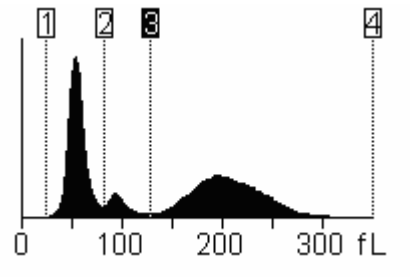


Figure7-24 Adjusting discriminator (1)

4. Press [←] to move the third discriminator to 100fL, as Figure7-25 shows;

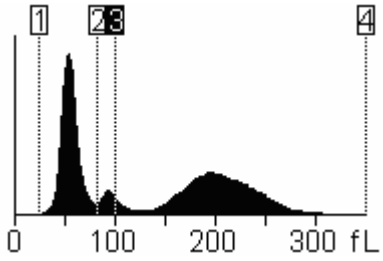


Figure7-25 Adjusting discriminator (2)

5. Press [ENTER] and a message box will pop up, as Figure7-26 shows.

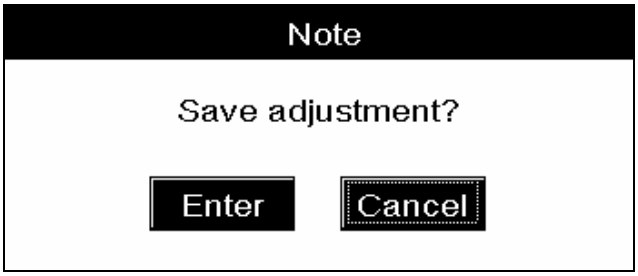


Figure7-26 "Note" message box

CLICK "**Enter**" to save the changes and return to the "**Sample Histogram Review**" screen;
CLICK "**Cancel**" to abort the changes and return to the "**Sample Histogram Review**" screen.

Printing sample results

Press [PRINT] to print out the current sample result.

7.3 Searching for Interested Sample Results

7.3.1 Starting a search

At the "**Sample Table Review**" screen, press [F1] of the external keyboard to enter the "**Search**"window, as Figure7-27 shows.

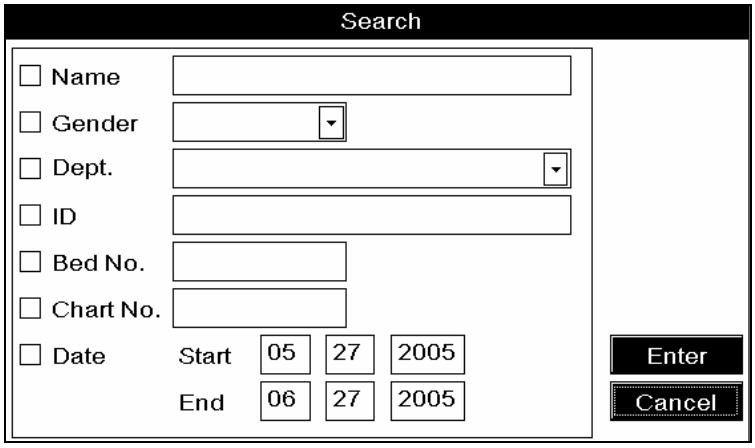


Figure7-27 "Search" window

To include a search condition, press [↑] or [↓] to move the cursor to the desired condition and press [ENTER] to tick the condition, as Figure7-28 shows.

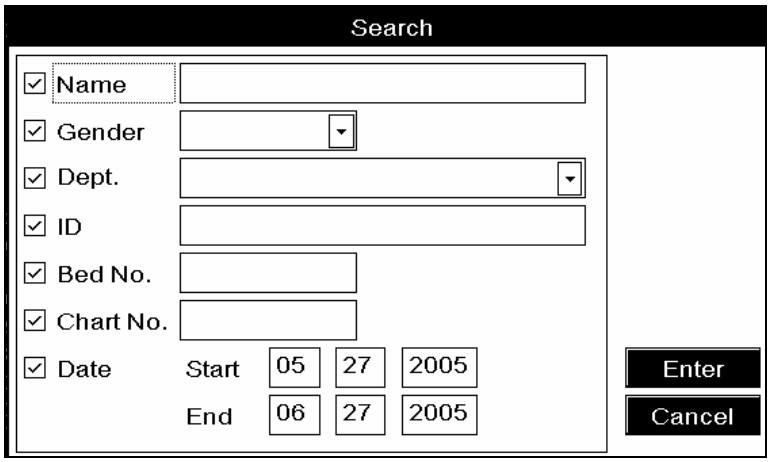


Figure7-28 All 7 search conditions are included

- Entering the patient name

ENTER the patient name into the "**Name**"box.

- Selecting patient gender

SELECT the desired item ***from the*** "**Gender**"***pull-down list***. Note that you can select blank

in case you are not aware of the patient gender.

- Entering the department name

You can either directly ***ENTER*** the name of the department, from which the sample came, into the "**Department**" box or ***SELECT*** the desired department ***from the*** "**Department**" ***pull-down list*** (if there are previously saved departments in the list).

- Entering sample ID

ENTER the ID number into the "**ID**" box.

- Entering bed number

ENTER the number of the patient's bed into the "**Bed No.**" box.

- Entering the chart number

ENTER the number of the patient's medical chart into the "**Chart No.**" box.

- Entering the start and end date

ENTER the start date into the "**Start**" box; ***ENTER*** the end date into the "**End**" box.

CLICK "**Enter**" to start the search. The analyzer will search the saved sample results for matches and report the conclusion, as Figure7-29 shows. ***CLICK*** "**Enter**" to return to the "**Sample Table Review**"screen.

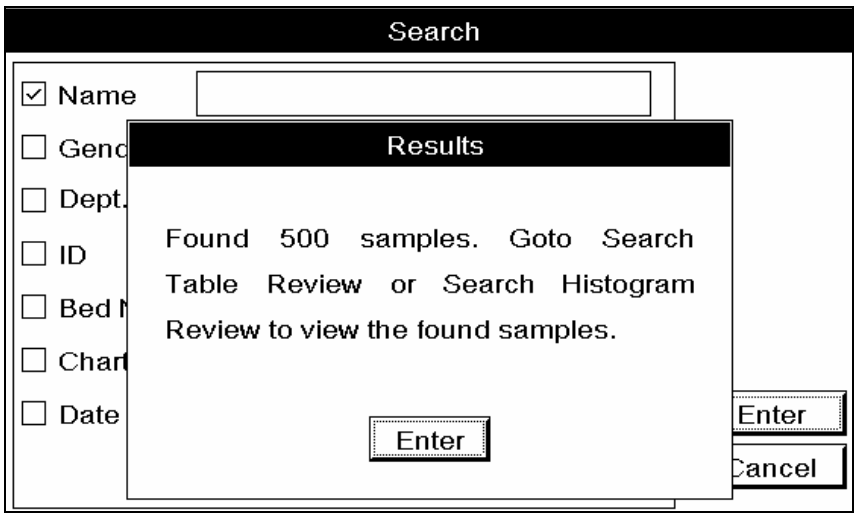


Figure7-29 Reporting conclusion of the search

7.3.2 Reviewing Search Result in the "Search Table Review" Mode

NOTE

- **For every search, the analyzer can display maximum 500 matches.**
- **The matches will be deleted if you have run another sample (including background check), or deleted a sample result, or restarted the analyzer after the search.**

Entering the "Sample Table Review" screen

Press [MENU] to enter the system menu. ***SELECT*** "**Review → Search Review → Search Table Review**" (Figure7-30), to enter the "**Search Table Review**" screen (Figure7-31).

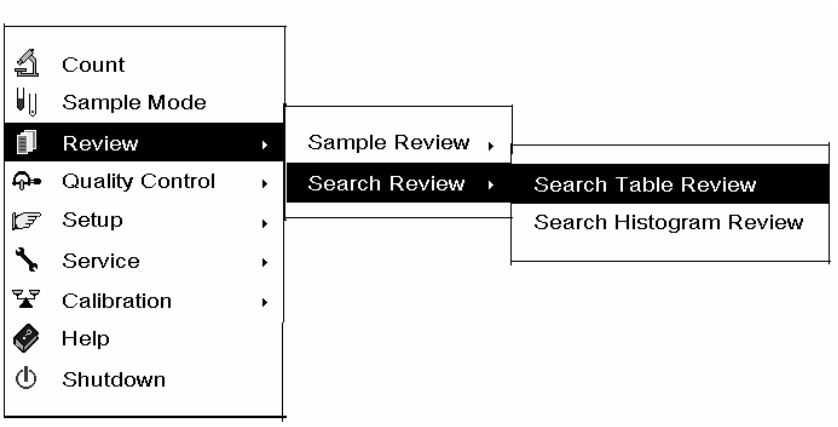
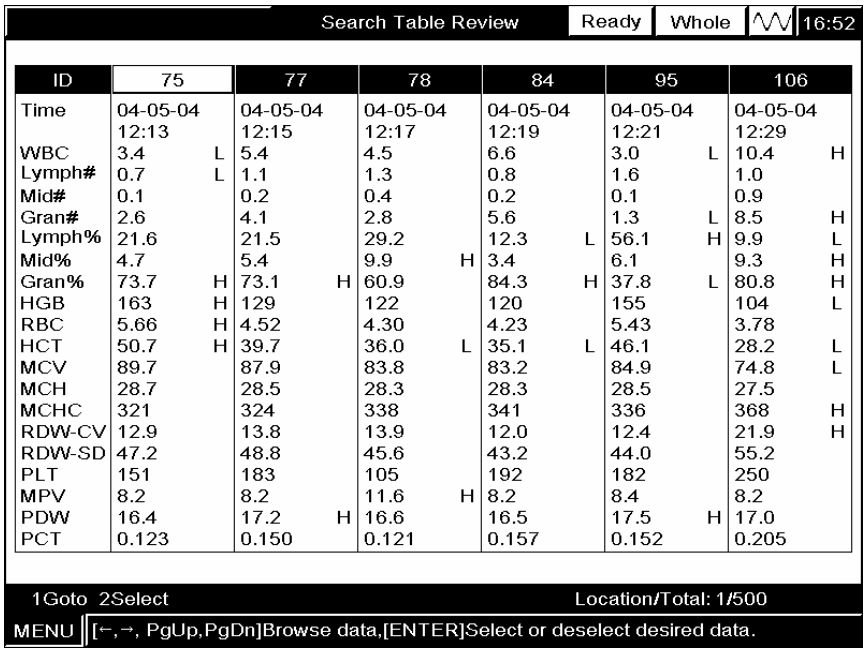


Figure7-30 System menu

The sample results are sequentially displayed on the screen, the earliest on the utmost left. The "**Location/Total**" displayed in the lower right corner of the screen indicates the location of the current sample result (the one whose "**ID**" is backlit) and the total number of the sample results matching the search conditions.



ID	75	77	78	84	95	106
Time	04-05-04 12:13	04-05-04 12:15	04-05-04 12:17	04-05-04 12:19	04-05-04 12:21	04-05-04 12:29
WBC	3.4 L	5.4	4.5	6.6	3.0 L	10.4 H
Lymph#	0.7 L	1.1	1.3	0.8	1.6	1.0
Mid#	0.1	0.2	0.4	0.2	0.1	0.9
Gran#	2.6	4.1	2.8	5.6	1.3 L	8.5 H
Lymph%	21.6	21.5	29.2	12.3 L	56.1 H	9.9 L
Mid%	4.7	5.4	9.9 H	3.4	6.1	9.3 H
Gran%	73.7 H	73.1 H	60.9	84.3 H	37.8 L	80.8 H
HGB	163 H	129	122	120	155	104 L
RBC	5.66 H	4.52	4.30	4.23	5.43	3.78
HCT	50.7 H	39.7	36.0 L	35.1 L	46.1	28.2 L
MCV	89.7	87.9	83.8	83.2	84.9	74.8 L
MCH	28.7	28.5	28.3	28.3	28.5	27.5
MCHC	321	324	338	341	336	368 H
RDW-CV	12.9	13.8	13.9	12.0	12.4	21.9 H
RDW-SD	47.2	48.8	45.6	43.2	44.0	55.2
PLT	151	183	105	192	182	250
MPV	8.2	8.2	11.6 H	8.2	8.4	8.2
PDW	16.4	17.2 H	16.6	16.5	17.5 H	17.0
PCT	0.123	0.150	0.121	0.157	0.152	0.205

Figure7-31 “Search Table Review” screen

Browsing sample results

Press [←] or [→] to browse the preceding or following sample result; press [PgUp] or [PgDn] to browse the preceding or following screen.

Switching to the “Search Histogram Review” mode

If you are interested in reviewing the histograms of the current sample result, press [6] to switch to the ”**Sample Histogram Review**” mode. To switch back to the “**Sample Table Review**” mode, press [6] again.

Jumping to a sample result with known location

Press [1] and a “**Goto**” window will pop up, as Figure7-32 shows.

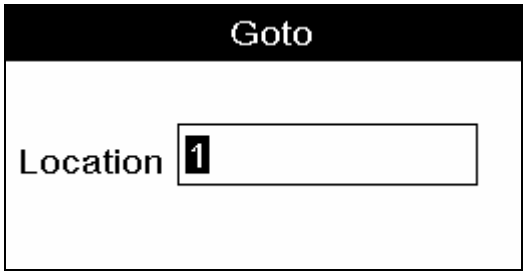


Figure7-32 “Goto” window

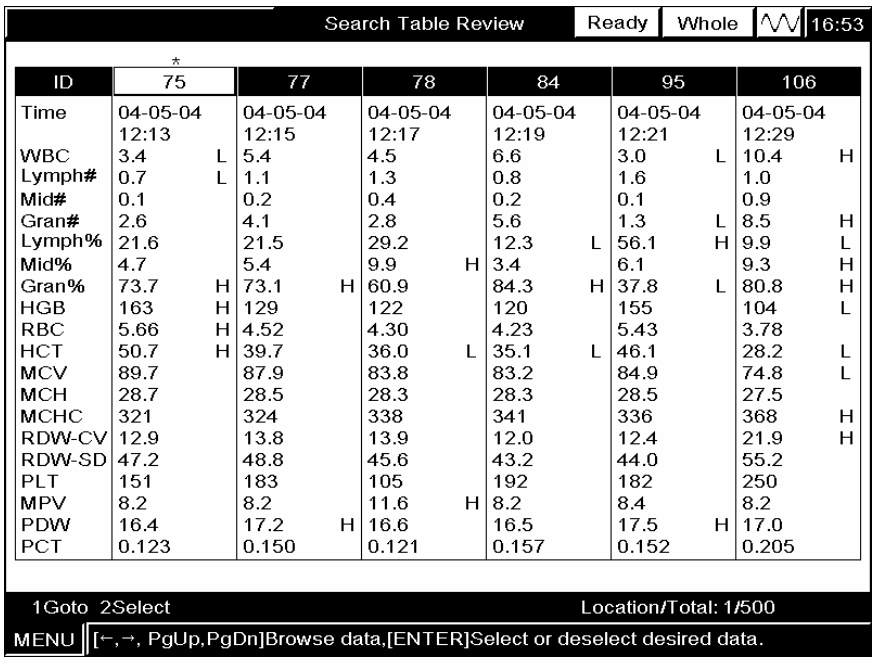
ENTER the location into the “**Location**” box and press [ENTER] to jump to the desired sample result.

Selecting/deselecting sample results

You can select certain interested samples for transmission or printing.

- Selecting/deselecting a sample result

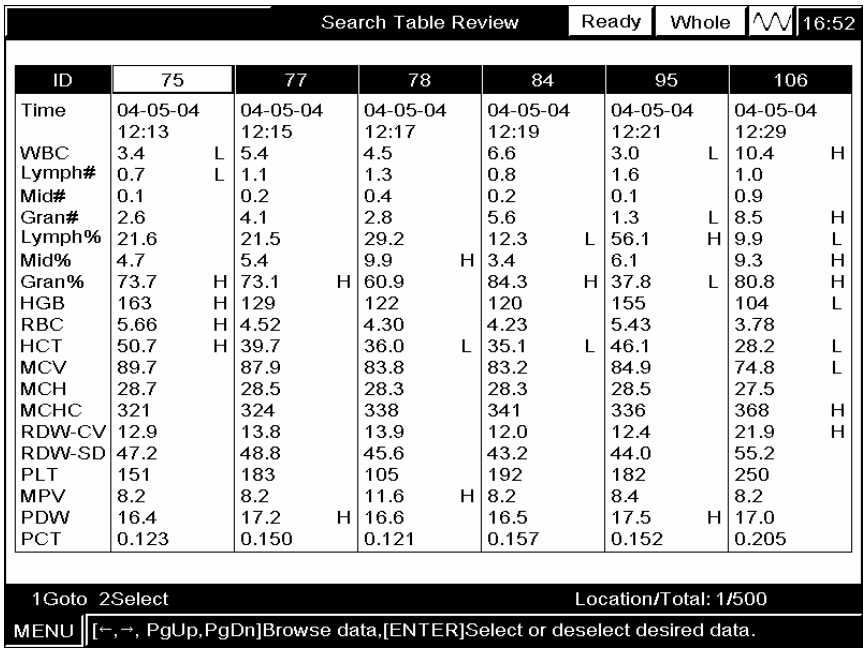
Press [←] or [→] to move the cursor to the interested sample result and press [ENTER] to select it. The selected sample result will be marked with a "*", as sample "75" in Figure7-33 shows.



ID	* 75		77		78		84		95		106	
Time	04-05-04 12:13		04-05-04 12:15		04-05-04 12:17		04-05-04 12:19		04-05-04 12:21		04-05-04 12:29	
WBC	3.4	L	5.4		4.5		6.6		3.0	L	10.4	H
Lymph#	0.7	L	1.1		1.3		0.8		1.6		1.0	
Mid#	0.1		0.2		0.4		0.2		0.1		0.9	
Gran#	2.6		4.1		2.8		5.6		1.3	L	8.5	H
Lymph%	21.6		21.5		29.2		12.3	L	56.1	H	9.9	L
Mid%	4.7		5.4		9.9	H	3.4		6.1		9.3	H
Gran%	73.7	H	73.1	H	60.9		84.3	H	37.8	L	80.8	H
HGB	163	H	129		122		120		155		104	L
RBC	5.66	H	4.52		4.30		4.23		5.43		3.78	
HCT	50.7	H	39.7		36.0	L	35.1	L	46.1		28.2	L
MCV	89.7		87.9		83.8		83.2		84.9		74.8	L
MCH	28.7		28.5		28.3		28.3		28.5		27.5	
MCHC	321		324		338		341		336		368	H
RDW-CV	12.9		13.8		13.9		12.0		12.4		21.9	H
RDW-SD	47.2		48.8		45.6		43.2		44.0		55.2	
PLT	151		183		105		192		182		250	
MPV	8.2		8.2		11.6	H	8.2		8.4		8.2	
PDW	16.4		17.2	H	16.6		16.5		17.5	H	17.0	
PCT	0.123		0.150		0.121		0.157		0.152		0.205	

Figure7-33 Selecting a sample result

Press [ENTER] again to deselect the sample result. Once the sample is deselected, the "*" will disappear, as sample "75" in Figure7-34 shows.



ID	75	77	78	84	95	106
Time	04-05-04 12:13	04-05-04 12:15	04-05-04 12:17	04-05-04 12:19	04-05-04 12:21	04-05-04 12:29
WBC	3.4 L	5.4	4.5	6.6	3.0 L	10.4 H
Lymph#	0.7 L	1.1	1.3	0.8	1.6	1.0
Mid#	0.1	0.2	0.4	0.2	0.1	0.9
Gran#	2.6	4.1	2.8	5.6	1.3 L	8.5 H
Lymph%	21.6	21.5	29.2	12.3 L	56.1 H	9.9 L
Mid%	4.7	5.4	9.9 H	3.4	6.1	9.3 H
Gran%	73.7 H	73.1 H	60.9	84.3 H	37.8 L	80.8 H
HGB	163 H	129	122	120	155	104 L
RBC	5.66 H	4.52	4.30	4.23	5.43	3.78
HCT	50.7 H	39.7	36.0 L	35.1 L	46.1	28.2 L
MCV	89.7	87.9	83.8	83.2	84.9	74.8 L
MCH	28.7	28.5	28.3	28.3	28.5	27.5
MCHC	321	324	338	341	336	368 H
RDW-CV	12.9	13.8	13.9	12.0	12.4	21.9 H
RDW-SD	47.2	48.8	45.6	43.2	44.0	55.2
PLT	151	183	105	192	182	250
MPV	8.2	8.2	11.6 H	8.2	8.4	8.2
PDW	16.4	17.2 H	16.6	16.5	17.5 H	17.0
PCT	0.123	0.150	0.121	0.157	0.152	0.205

Figure7-34 Deselecting a patient result

- Selecting/deselecting multiple sample results

Example 6：To select the sample results of locations 1 – 5 (sample ID: 75, 77, 78, 84, 95, 106 in Figure7-35), follow the procedure below to do so:

1. Press [3] to enter the "**Select**" window, as Figure7-35 shows;

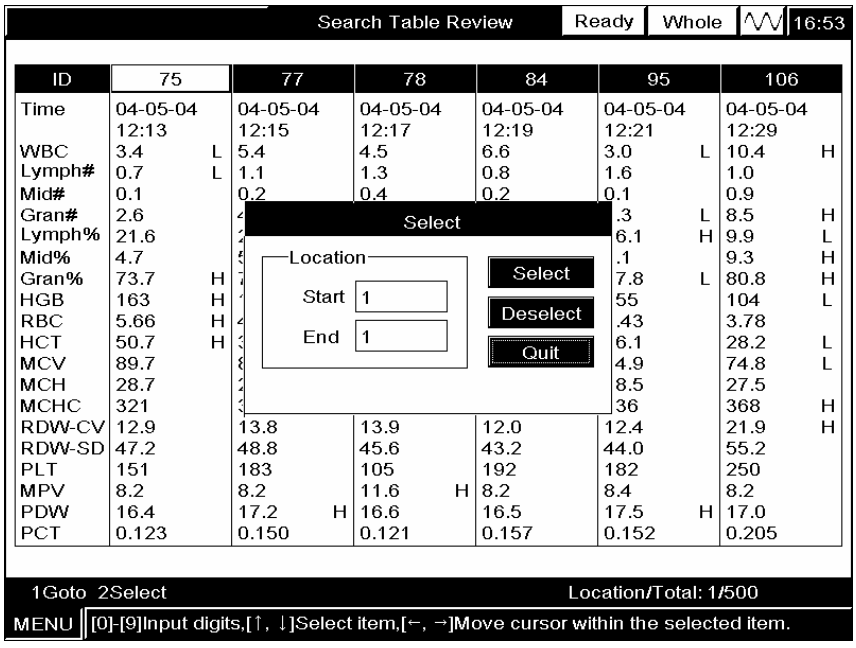


Figure7-35 Entering the "Select" window

2. ***ENTER*** the start position ("**1**") into the **"Start**" box;

3. ***ENTER*** the start position ("**5**") into the "**End**" box;

4. ***CLICK*** "**Select**" and the lower left corner of the "**Select**" window will display "**Results selected**", as Figure7-36 shows;

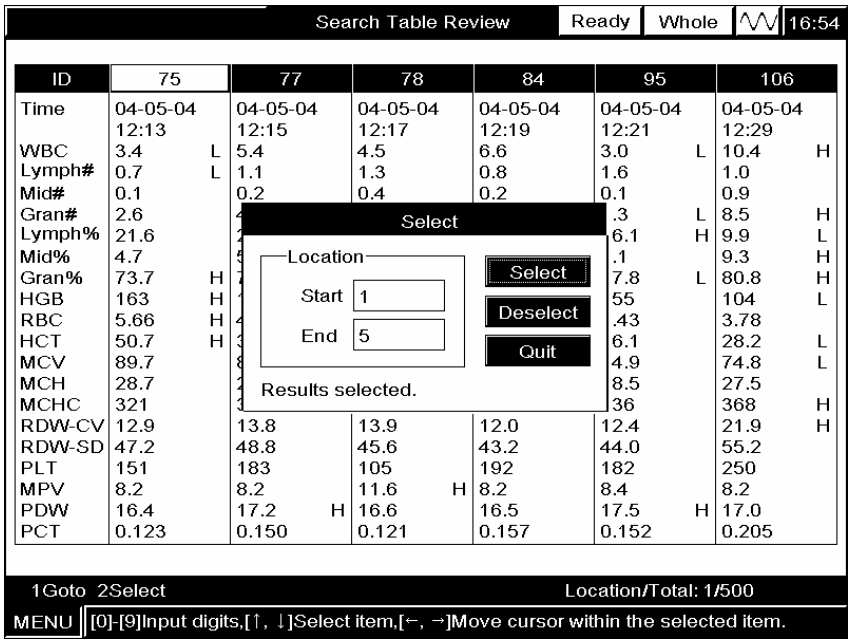
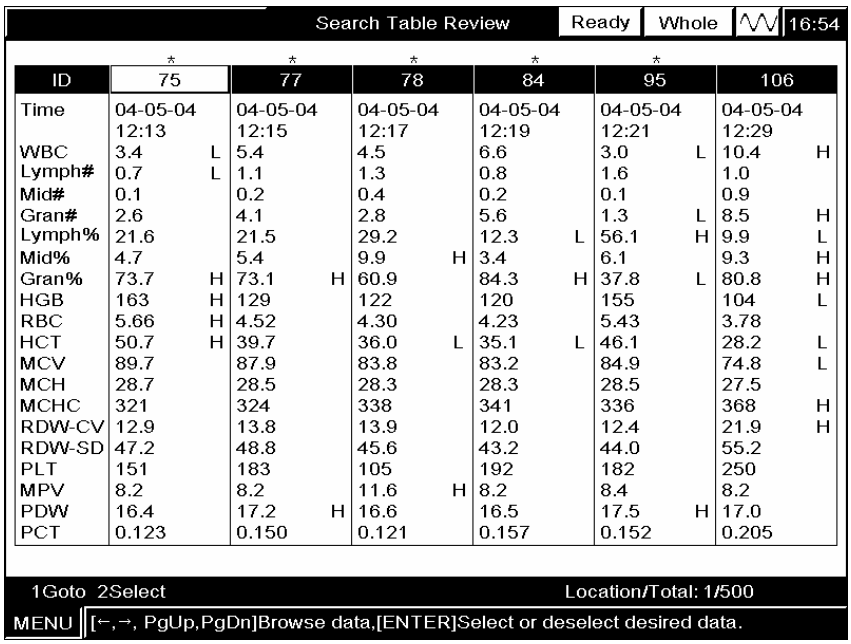


Figure7-36 Selecting sample results of locations 1- 5

5. ***CLICK*** "**Quit**" to return to the "**Sample Table Review**" screen. The selected sample results will be marked with "*", as Figure7-37 shows.



ID	75		77		78		84		95		106	
Time	04-05-04 12:13		04-05-04 12:15		04-05-04 12:17		04-05-04 12:19		04-05-04 12:21		04-05-04 12:29	
WBC	3.4	L	5.4		4.5		6.6		3.0	L	10.4	H
Lymph#	0.7	L	1.1		1.3		0.8		1.6		1.0	
Mid#	0.1		0.2		0.4		0.2		0.1		0.9	
Gran#	2.6		4.1		2.8		5.6		1.3	L	8.5	H
Lymph%	21.6		21.5		29.2		12.3	L	56.1	H	9.9	L
Mid%	4.7		5.4		9.9	H	3.4		6.1		9.3	H
Gran%	73.7	H	73.1	H	60.9		84.3	H	37.8	L	80.8	H
HGB	163	H	129		122		120		155		104	L
RBC	5.66	H	4.52		4.30		4.23		5.43		3.78	
HCT	50.7	H	39.7		36.0	L	35.1	L	46.1		28.2	L
MCV	89.7		87.9		83.8		83.2		84.9		74.8	L
MCH	28.7		28.5		28.3		28.3		28.5		27.5	
MCHC	321		324		338		341		336		368	H
RDW-CV	12.9		13.8		13.9		12.0		12.4		21.9	H
RDW-SD	47.2		48.8		45.6		43.2		44.0		55.2	
PLT	151		183		105		192		182		250	
MPV	8.2		8.2		11.6	H	8.2		8.4		8.2	
PDW	16.4		17.2	H	16.6		16.5		17.5	H	17.0	
PCT	0.123		0.150		0.121		0.157		0.152		0.205	

Figure7-37 Reviewing the selected results

Example 7：To deselect the sample results of locations 1 – 5 (sample ID: 75, 77, 78, 84, 95, 106 in Figure7-38), follow the procedure below to do so:

1. Enter the start and end positions as instructed in steps 1 – 3 of Example 6;
2. ***CLICK*** "**Deselect**" and the lower left corner of the "**Select**" window will display "**Results deselected**", as Figure7-38 shows;

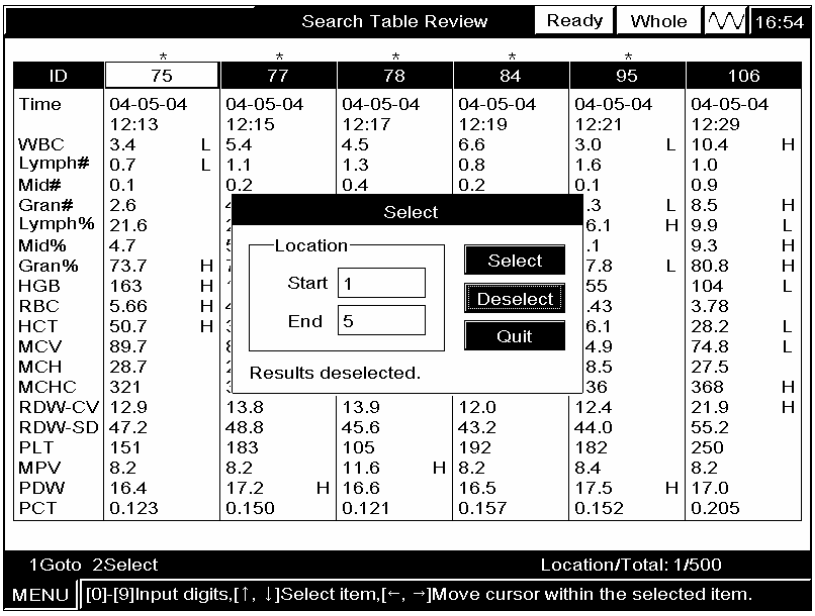


Figure7-38 Deselecting the sample results of locations 1 – 5

3. ***CLICK*** "**Quit**" to return to the "**Sample Table**" screen. The "*" above those sample results will disappear, as Figure7-39 shows.

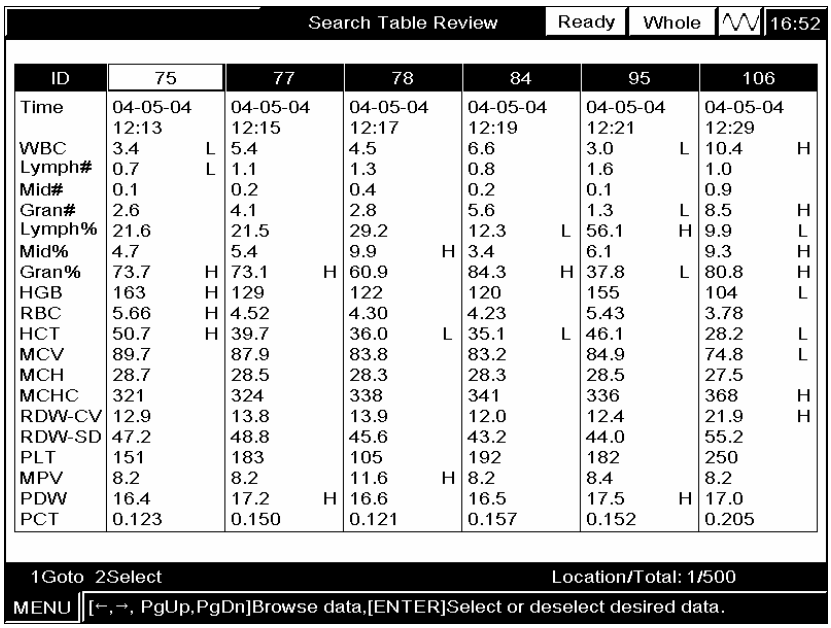
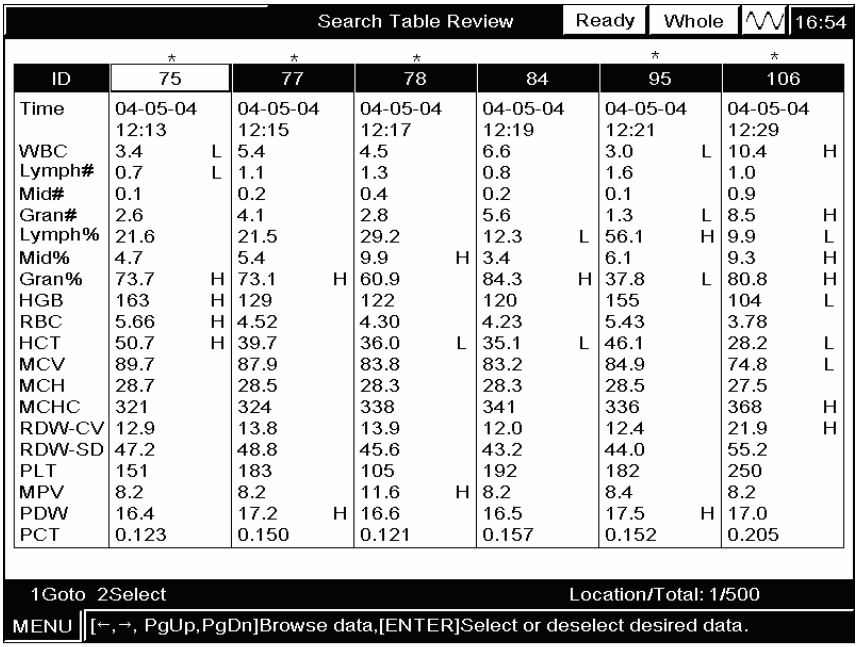


Figure7-39 Reviewing the deselected results

Example 8: To select the sample results of locations 1 to 3 and 5 to 6, follow the procedure below to do so:

1. Select the sample results of locations 1 to 3 as instructed in steps 1 to 5 of Example 6;
2. Select the sample results of locations 5 to 6 as instructed in steps 1 to 5 of Example 6;
3. ***CLICK*** "**Quit**" to return to the "**Sample Table Review**" screen. The selected sample results will be marked with "*", as Figure7-40 shows.

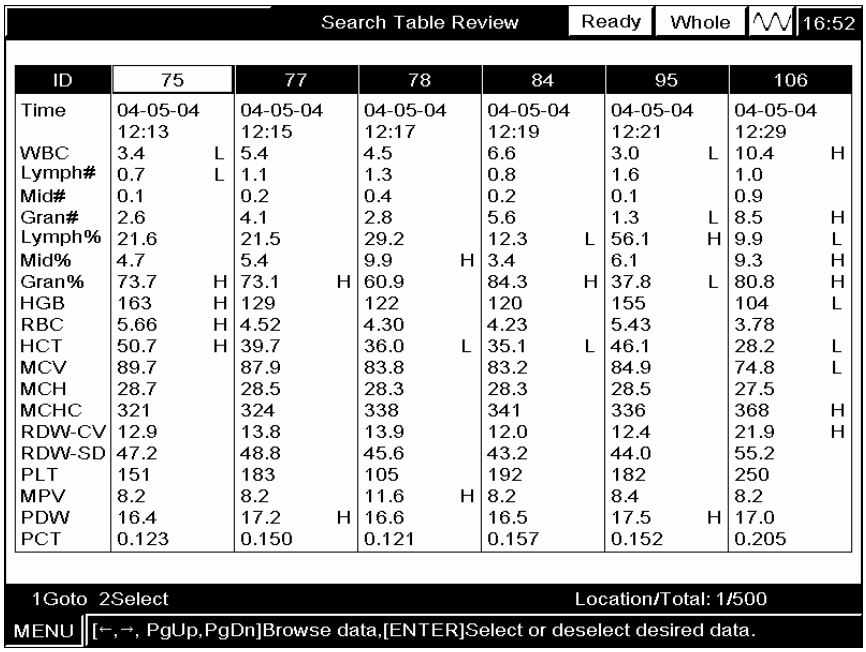


ID	* 75		* 77		* 78		84		* 95		* 106	
Time	04-05-04 12:13		04-05-04 12:15		04-05-04 12:17		04-05-04 12:19		04-05-04 12:21		04-05-04 12:29	
WBC	3.4	L	5.4		4.5		6.6		3.0	L	10.4	H
Lymph#	0.7	L	1.1		1.3		0.8		1.6		1.0	
Mid#	0.1		0.2		0.4		0.2		0.1		0.9	
Gran#	2.6		4.1		2.8		5.6		1.3	L	8.5	H
Lymph%	21.6		21.5		29.2		12.3	L	56.1	H	9.9	L
Mid%	4.7		5.4		9.9	H	3.4		6.1		9.3	H
Gran%	73.7	H	73.1	H	60.9		84.3	H	37.8	L	80.8	H
HGB	163	H	129		122		120		155		104	L
RBC	5.66	H	4.52		4.30		4.23		5.43		3.78	
HCT	50.7	H	39.7		36.0	L	35.1	L	46.1		28.2	L
MCV	89.7		87.9		83.8		83.2		84.9		74.8	L
MCH	28.7		28.5		28.3		28.3		28.5		27.5	
MCHC	321		324		338		341		336		368	H
RDW-CV	12.9		13.8		13.9		12.0		12.4		21.9	H
RDW-SD	47.2		48.8		45.6		43.2		44.0		55.2	
PLT	151		183		105		192		182		250	
MPV	8.2		8.2		11.6	H	8.2		8.4		8.2	
PDW	16.4		17.2	H	16.6		16.5		17.5	H	17.0	
PCT	0.123		0.150		0.121		0.157		0.152		0.205	

Figure7-40 Reviewing the selected results

Example 9：To deselect the sample results of locations 1 to 3 and5 to 6, follow the procedure below to do so:

1. Deselect the sample results of locations 1 to 3 as instructed in steps 1 to 3 of Example 7;
2. Deselect the sample results of locations 5 to 6 as instructed in steps 1 to 3 of Example 7;
3. ***CLICK*** "**Quit**" to return to the "**Sample Table Review**" screen. The "*" above those sample results will disappear, as Figure7-41 shows.



ID	75		77		78		84		95		106	
Time	04-05-04 12:13		04-05-04 12:15		04-05-04 12:17		04-05-04 12:19		04-05-04 12:21		04-05-04 12:29	
WBC	3.4	L	5.4		4.5		6.6		3.0	L	10.4	H
Lymph#	0.7	L	1.1		1.3		0.8		1.6		1.0	
Mid#	0.1		0.2		0.4		0.2		0.1		0.9	
Gran#	2.6		4.1		2.8		5.6		1.3	L	8.5	H
Lymph%	21.6		21.5		29.2		12.3	L	56.1	H	9.9	L
Mid%	4.7		5.4		9.9	H	3.4		6.1		9.3	H
Gran%	73.7	H	73.1	H	60.9		84.3	H	37.8	L	80.8	H
HGB	163	H	129		122		120		155		104	L
RBC	5.66	H	4.52		4.30		4.23		5.43		3.78	
HCT	50.7	H	39.7		36.0	L	35.1	L	46.1		28.2	L
MCV	89.7		87.9		83.8		83.2		84.9		74.8	L
MCH	28.7		28.5		28.3		28.3		28.5		27.5	
MCHC	321		324		338		341		336		368	H
RDW-CV	12.9		13.8		13.9		12.0		12.4		21.9	H
RDW-SD	47.2		48.8		45.6		43.2		44.0		55.2	
PLT	151		183		105		192		182		250	
MPV	8.2		8.2		11.6	H	8.2		8.4		8.2	
PDW	16.4		17.2	H	16.6		16.5		17.5	H	17.0	
PCT	0.123		0.150		0.121		0.157		0.152		0.205	

Figure7-41 Reviewing the deselected results

Printing sample results

Select the sample results you want to print and press [PRINT]. A message box will pop up to ask you to confirm the printing, as Figure7-42 shows. ***CLICK*** "**Ente**r" to print out all the selected results; ***CLICK*** "**Cancel**" to abort the printing.

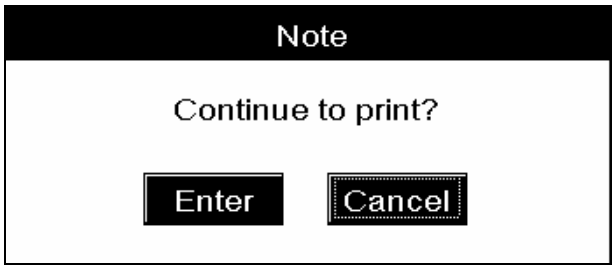


Figure7-42 Print message box

Calculating reproducibility

This analyzer provides three reproducibility indices Mean, SD（Standard Deviation）and CV%（Coefficient of Variation）.

$$\text{Mean} = \frac{\sum_{i=1}^{n} X_i}{n}$$

$$SD = \sqrt{\frac{\sum (X_i - Mean)^2}{n-1}}$$

$$CV\% = \frac{SD}{Mean} \times 100$$

Where n represents how many sample results are selected and X_i is the result of the i^{th} analysis.

To check the reproducibility of the selected sample results, select at least three sample results and press [7] to view the reproducibility. If any selected result contains invalid parameter value (s), the reproducibility indices of that parameter(s) will also be invalid (***).

To print out the displayed indices, press [PRIINT]. To exit the "**Reproducibility**" screen, press [MENU] to exit the "**Reproducibility**"screen.

7.3.3 Reviewing Search Result in the "Search Histogram Review" Mode

NOTE

- **For every search, the analyzer can display maximum 500 matches.**
- **The matches will be deleted if you have run another sample (including background check), or deleted a sample result, or restarted the analyzer after the search.**

Entering the "Search Histogram Review"screen

Press [MENU] to enter the system menu.

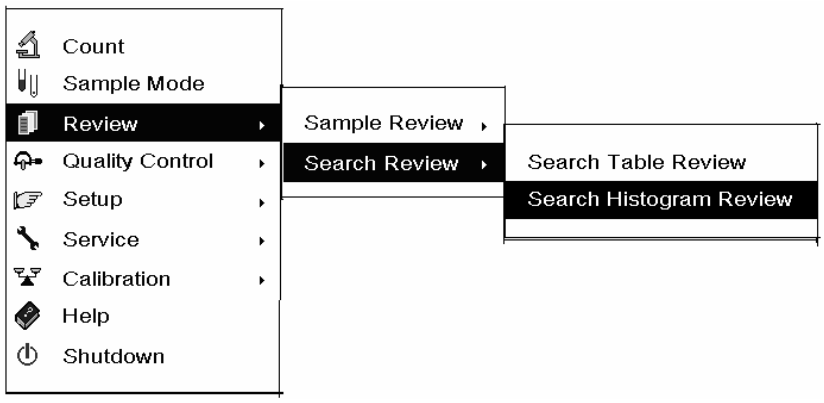


Figure7-43 System menu

SELECT "**Review → Search Review → Search Histogram Review**" (Figure7-43) to enter the "**Search Histogram Review**" screen (Figure7-44). The sample information will be displayed at the top of the screen, followed by the parameter values and histograms. The "**Location/Total**" displayed in the upper right corner of the screen indicates the location of the current sample result and the total number of the saved sample results.

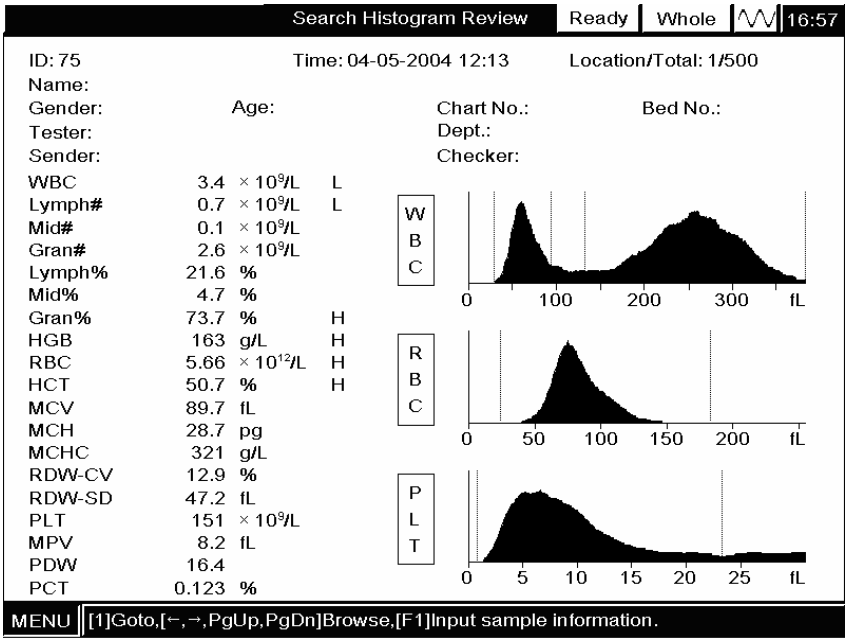


Figure7-44 "Sample Histogram Review" screen

Browsing sample results

Press [←] or [→] to browse the preceding or following sample result; press [PgUp] or [PgDn] to jump 6 locations (e.g. jumping from location 1 to location 7).

Switching to the "Search Table Review" mode

To switch to the "**Search Table Review**" mode, press [6]; to switch back to the "**Search Histogram Review**" mode, press [6] again.

Jumping to a sample result with known location

Press [1] and a "**Goto**" window will pop up, as Figure7-45 shows.

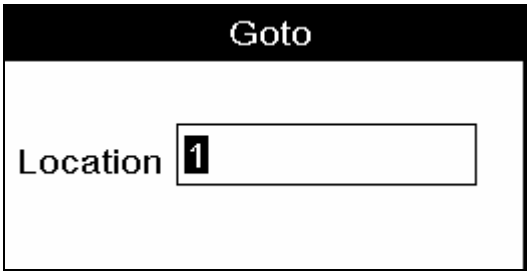


Figure7-45 "Goto" window

ENTER the location into the "**Location**" box and press [ENTER] to jump to the desired sample result.

Editing sample information

Press [F1] to edit the sample information, Figure7-46 shows.

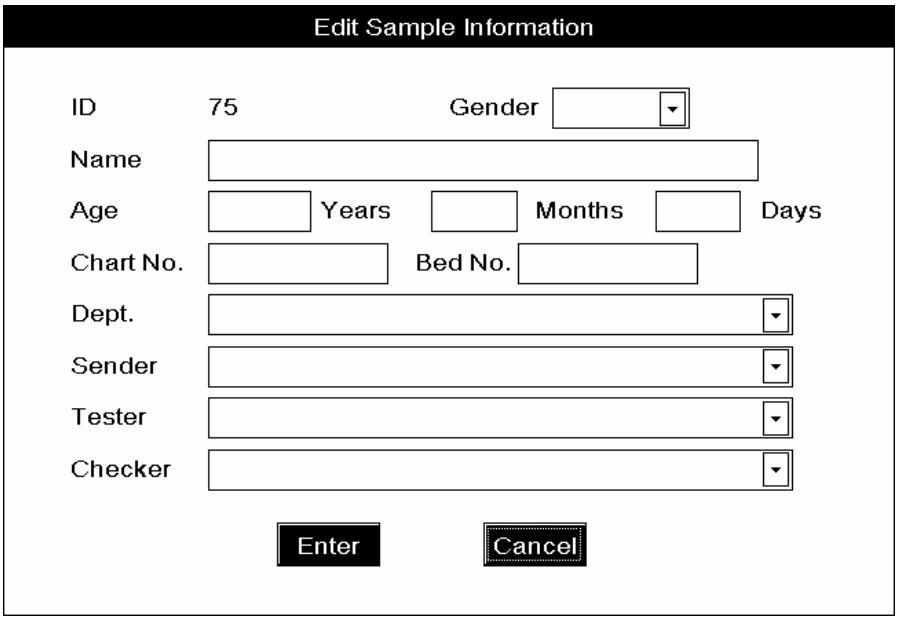


Figure7-46 Editing sample information

- ID

You cannot edit the sample ID of an analyzed sample.

- Selecting patient gender

SELECT the desired item ***from the*** **"Gender"** ***pull-down list***. Note that you can select blank in case you are not aware of the patient gender.

- Entering the patient name

ENTER the patient name into the "**Name**" box.

- Entering the patient age

This analyzer provides three ways for you to enter the patient age –in years, in months and in days. The first way is designed for the adult or pediatric patients no younger than one year; the second for the infant patients one month to one year; the third for the neonatal patients no older than 28 days. You can choose only one of the three ways to enter the patient age.

To enter the patient age in years：***ENTER*** the desired number, an integer from 0 to 200, into the "**Years**" box.
To enter the patient age in months： ***ENTER*** the desired number, an integer from 0 to 12, into the "**Months**" box.
To enter the patient age in days：***ENTER*** the desired number, an integer from 0 to 31, into the "**Days**" box.

- Entering the chart number

ENTER the number of the patient's medical chart into the "**Chart No.**" box.

- Entering the bed number

ENTER the number of the patient's bed into the "**Bed No.**" box.

- Entering the department name

You can either directly ***ENTER*** the name of the department, from which the sample came, into the "**Department**" box or ***SELECT*** the desired department **from the** "**Department**" **pull-down list** (if there are previously saved departments in the list).

- Entering the names of the sender, tester and reviewer

To enter the name of the person who sent the sample for analysis, ***ENTER*** the name into the "**Sender**" box or ***SELECT*** the desired name **from the** "**Sender**" **pull-down list** (if there are previously saved names in the list)；to enter the name of the person who ran the sample, ***ENTER*** the name into the "**Tester**" box or ***SELECT*** the desired name **from the** "**Tester**" **pull-down list** (if there are previously saved names in the list)；to enter the name of the person who reviewed the sample results, ***ENTER*** the name into the "**Reviewer**" box, or ***SELECT*** the desired name **from the** "**Reviewer**" **pull-down list** (if there are previously saved names in the list). All the three pull-down lists are capable of saving 30 entered names.

- "**Enter**" button

When you have finished entering all the interested sample information, ***CLICK*** the "**Enter**" button (or press [F4] of the external keyboard) to save the changes and return to the "**Search Histogram Review**" screen.

- "**Cancel**" button

If you do not want to save the entered information, ***CLICK*** the "**Cancel**" button to return to the "**Search Histogram Review**" screen without saving the changes.

Adjusting histograms

If you are not satisfied with the obtained histograms, you can adjust them manually, provided you have the administrator password.

The first three discriminators of the WBC histogram are adjustable. Note that if the WBC result is less than 0.5 or non-numeric (***), the WBC histogram is not adjustable. The first two discriminators of the RBC histogram are adjustable. Note that if the RBC result is less than 0.2 or non-numeric (***), the RBC histogram is not adjustable. The first two discriminators of the PLT histogram are adjustable. Note that if the PLT result is less than 10 or non-numeric (***), the PLT histogram is not adjustable.

Example10：To move the third discriminator of the following WBC histogram to 100fL, follow the procedure below to do so.

1. Press [ENTER] and the discriminator will become adjustable. See Figure7-47;

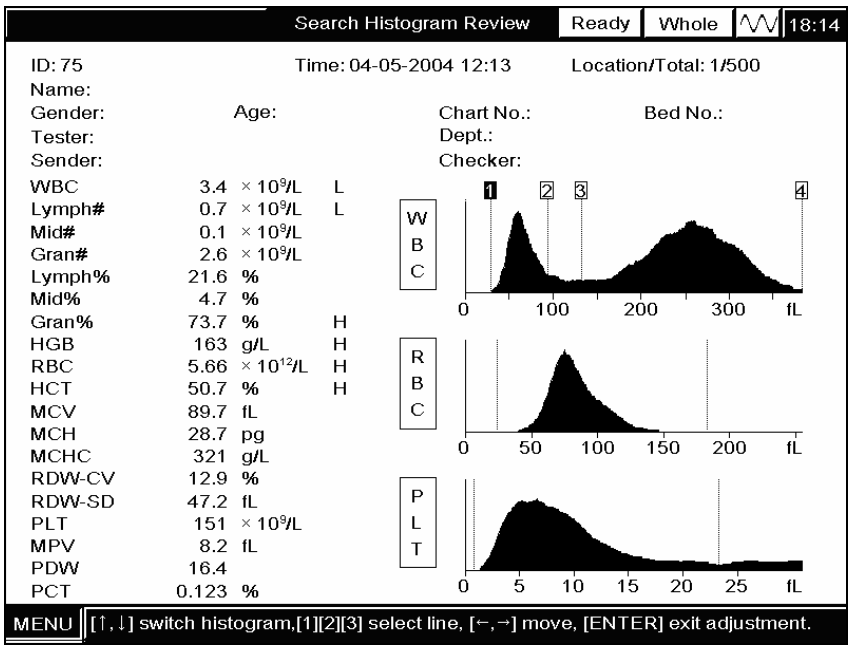


Figure7-47 WBC histogram with adjustable discriminators

2. Press [↑] or [↓] to select the WBC histogram;

3. Press [3] to select the third discriminator, as Figure7-48 shows;

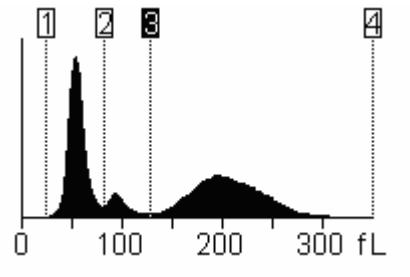


Figure7-48 Adjusting discriminator (1)

4. Press [←] to move the third discriminator to 100fL, as Figure7-49 shows;

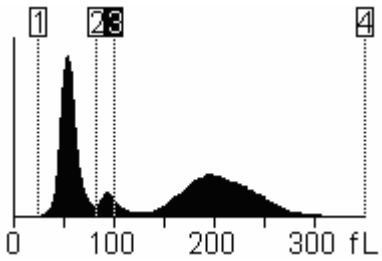


Figure7-49 Adjusting discriminator (2)

5. Press [ENTER] and a message box will pop up, as Figure7-50 shows.

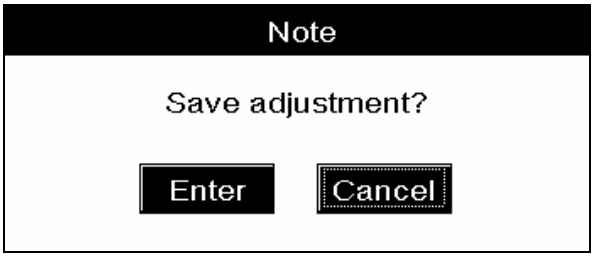


Figure7-50 The message box to ask you to save the changes

CLICK "**Ente**r" to save the changes and return to the "**Search Histogram Review**" screen;
CLICK "**Cancel**" to abort the changes and return to the "**Search Histogram Review**" screen.

Printing sample results

Press [PRINT] to print out the current sample result.

8 Using the QC Programs

8.1 Introduction

Quality Control (QC) consists of strategies and procedures that measure the precision and stability of the analyzer. The results imply the reliability of the sample results. QC involves measuring materials with known, stable characteristics at frequent intervals. Analysis of the results with statistical methods allows the inference that sample results are reliable. Mindray recommends you run the QC program daily with low, normal and high level controls. A new lot of controls should be analyzed in parallel with the current lot prior to their expiration dates. This may be accomplished by running the new lot of controls twice a day for five days using any empty QC files. The QC files calculate the mean, standard deviation and coefficient of variation for each selected parameter. The instrument-calculated means of these ten runs should be within the expected ranges published by the manufacturer.

The BC-3000 Plus provides 4 QC programs: L-J Analysis, $\overline{X}$ Analysis, $\overline{X}$-R Analysis and X-B Analysis.

8.2 “L-J Analysis” Program

Using the “**L-J Analysis**” program, you can provide quality control for maximum 12 parameters. The analyzer provides 9 QC files for you to save QC settings and results. Every QC file can save results of maximum 31 QC runs. When the saved QC results have reached the maximum number, the newest result will overwrite the oldest. The following introduction will use “**File 1**” as the example.

8.2.1 Editing L-J Settings

- Entering the “L-J Edit” screen

Press [MENU] to enter the system menu.

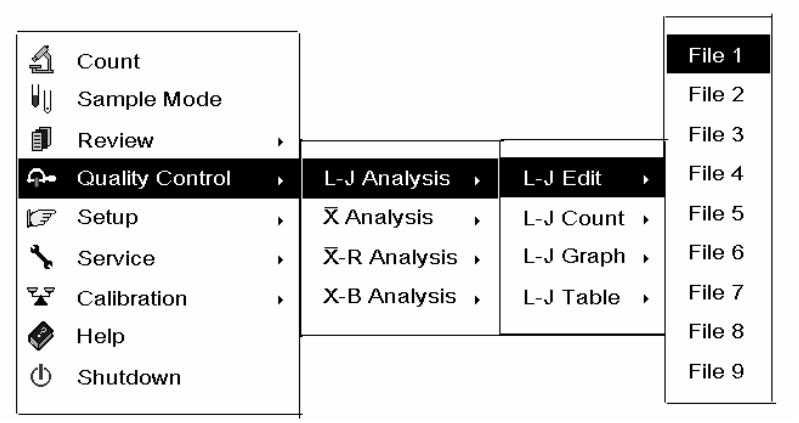


Figure8-1 System menu

SELECT “**Quality Control→ L-J Analysis → L-J Edit → File 1**” （Figure8-1）to enter the “**L-J Edit**” screen (Figure8-2).

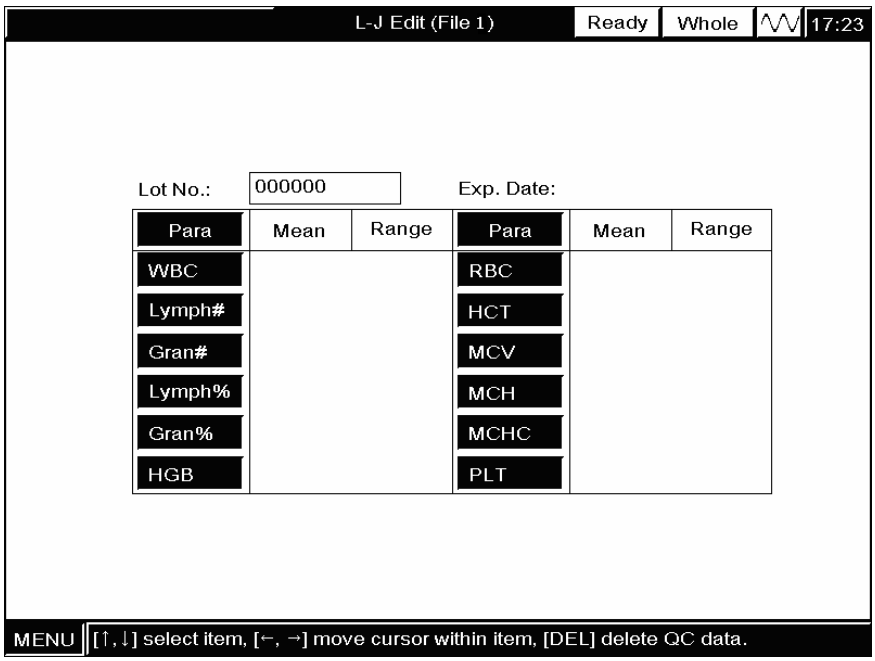


Figure8-2 "L-J Edit" screen

If there are saved L-J results and settings, you need to delete them first. Press [DEL] and a message box will pop up to confirm the deletion, as Figure8-3 shows.

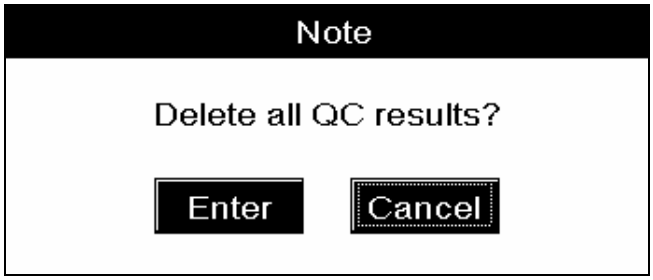


Figure8-3 A message box to confirm the deletion

***CLICK* "Enter"**to confirm the deletion; ***CLICK* "Cancel"**to abort the deletion.

- Entering lot number

ENTER the lot number of the control to be used into the "**Lot No.**" box.

- Entering Exp. Date

ENTER the expiration date of the control to be used into the "**Exp. Date**" box.

- Entering the expected results (mean) and limits (range)

ENTER the expected results (mean) and limits (range) respectively into the "**Mean**" and "**Range**" boxes of the parameters to be included in the L-J analysis.

NOTE

- **Refer to the instructions of use of the control for information on the lot number, expiration date, open-vial stability days, expected results and limits.**
- **The entered expiration date should be either the expiration date printed on the labeling or the open-vial expiration date, whichever is earlier.**
- **The open-vial expiration date is calculated as follows: the date that vial is opened + the open-vial stability days.**
- **At the "L-J Edit" screen, if you want to correct an erroneous entry, *MODIFY* the wrong digit.**

■ Deleting settings

Press [DEL] to delete all the settings.

■ Printing settings

Press [Print] to print out all the settings.

■ Exiting the "**L-J Edit**" screen

Press [MENU] to exit to the system menu; press [MAIN] to exit to the "**Count**" screen.
A message box shown in Figure8-4 will pop up, if :
There is a parameter for which you have entered only the expected result or the limit;
or
There is a parameter whose expected result is less than or equal to the limit.

***CLICK* "Enter"** to close the box and clear the erroneous entries. Re-enter the correct values before trying to exit the screen again. The settings can be saved only when both the expected result and limit are valid.

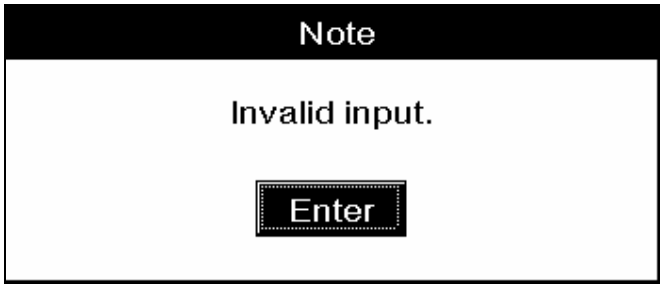


Figure8-4 An "Invalid input"message box

In case of any invalid entries of expiration dates, a message box will pop up to remind you of the error, as Figure8-5 shows. ***CLICK*** "**Enter**" to close the box and clear the erroneous entries. Re-enter the correct values before trying to exit the screen again.

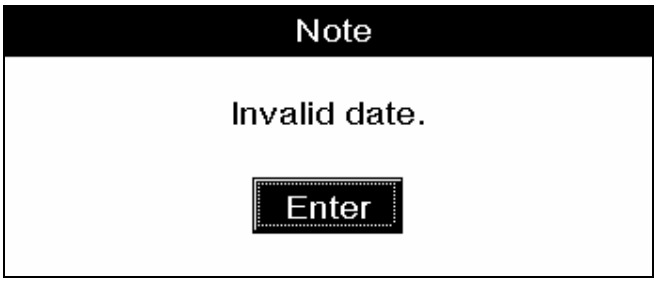


Figure8-5 An"Invalid date"message box

If all the entries are correct, a message box will pop up to remind you to save the changes, as Figure8-6 shows. ***CLICK*** *"**Enter**"* to save the changes and exit to the system menu (or the **"Count"** screen); ***CLICK*** "**Cancel**" to abort the changes and exit to the system menu (or the **"Count"** screen).

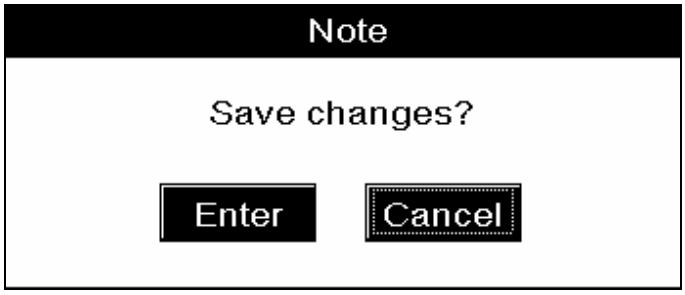


Figure8-6 A message box to confirm the changes

8.2.2 Running the Controls

- Selecting the "**Whole Blood**" mode

Press [MENU] and ***SELECT*** **"Mode"** to enter the "**Sample Mode**"screen. ***SELECT*** "**Whole Blood**" ***from the "Sample Mode" pull-down list***.

- Entering the **"L-J Count**" screen

Press [MENU] to enter the system menu. ***SELECT*** "**Quality Control→L-J Analysis → L-J Count →File 1**" to enter the "**L-J Count**"screen, as Figure 8-7 shows.

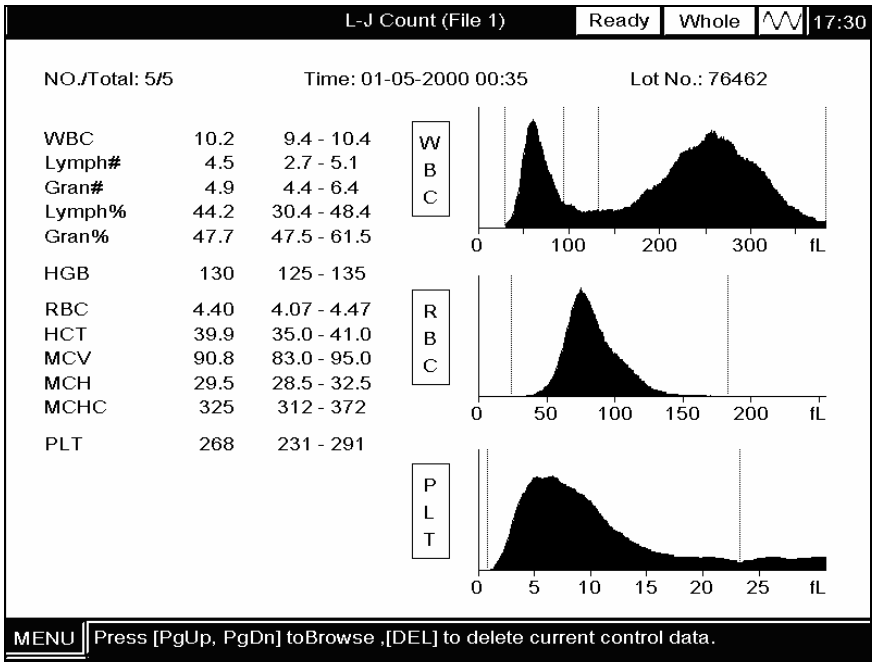


Figure 8-7 "L-J Count"screen

NOTE

- **Be sure to use the Mindray - specified controls. Using controls other than the specified will lead to misleading results.**
- **Refer to the instructions of use of the controls for how to store and use the controls.**

- **Samples, controls, calibrators and waste are potentially infectious. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them in the laboratory.**

⚠ WARNING

- **The sample probe tip is sharp and may contain biohazardous materials. Exercise caution to avoid contact with the probe when working around it.**
- **Do not re-use such disposable product as collection tubes, test tubes, capillary tubes, etc.**

NOTE

- **When switching from the Predilute mode to the Whole Blood mode, the analyzer will automatically flush the fluidic system.**
- **Be sure to keep the sample probe tip away from the tube bottom, otherwise the aspiration volume may be inaccurate.**
- **When the aspiration is done, remove the sample tube only when the sample probe is out of the tube.**

■ Running the controls

1. Be sure the **System Status** area displays "**Ready**" and **Count Mode** area displays "**Whole**".
2. Present a vial of control to the sample probe so that the tip is well into the vial, and press the aspirate key. The **System Status** area will display "**Running**" and the analyzer will start aspirating sample.
3. When you hear the beep and the sample probe is out of the vial, remove the vial. The sample probe will retract into the analyzer and the analysis progress will be displayed on the screen.
4. When the analysis is finished, the result will be displayed on the screen and the "**NO./Total**" in the upper left corner of the screen will automatically increase by 1 and the sample probe will be replaced.

NOTE

- **If the analyzer detects WBC/RBC clogging or bubbles during the analysis, the corresponding error messages will be displayed in the upper left corner of the screen and the results of all the related parameters will be invalidated. See Chapter 11 Troubleshooting for solutions.**
- **If the ambient temperature is outside the specified operating range, the analyzer will alarm you for abnormal ambient temperature and the analysis results may be unreliable. See Chapter 11 Troubleshooting for solutions.**

■ Browsing results of other L-J analyses

To browse the result of the preceding or following L-J analysis, press [PgUp] or [PgDn].

- Deleting L-J results

To delete the current result, press [DEL] and a message box will pop up, as Figure8-8 shows. ***CLCIK*** "**Enter**" to confirm the deletion; ***CLICK*** "**Cancel**" to abort the deletion.

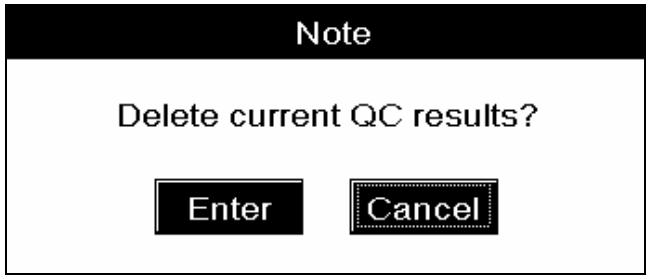


Figure8-8 A message box to confirm the deletion

- Printing L-J results

Press [PRINT] to print out the current QC result by the printer.

- Exiting the "**L-J Count**" screen

Press [MENU] to exit to the system menu, or press [MAIN] to exit to the "**Count**" screen.

8.2.3 Reviewing L-J Results

You can review the saved L-J results in either the "**L-J Graph**" mode or "**L-J Table**" mode.

"L-J Graph" mode

- Entering the "**L-J Graph**" screen

Press [MENU] to enter the system menu.

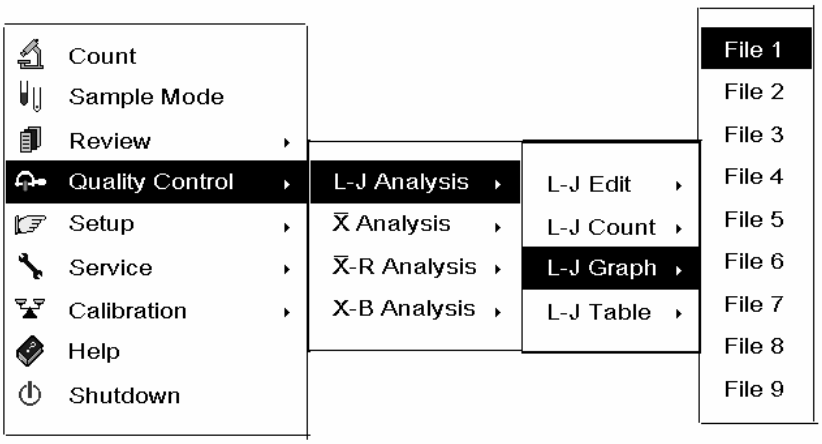


Figure8-9 System menu

SELECT "**Quality Control→ L-J Analysis→ L-J Graph→ File 1**"(Figure8-9) to enter the "**L-J Graph**" screen (Figure 8-10).

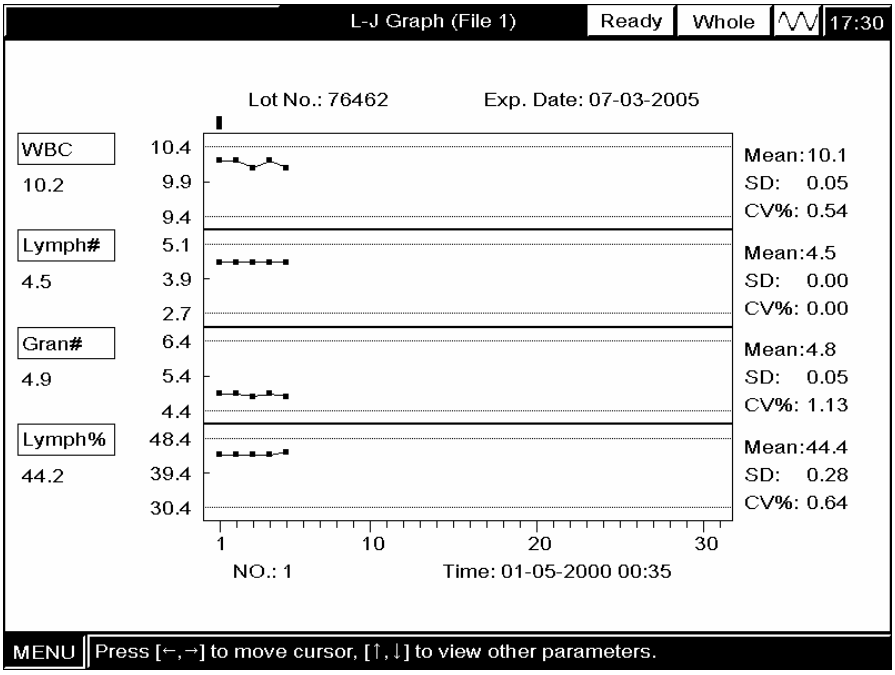


Figure 8-10 "L-J Graph"screen 1

The 12 parameters are displayed on three screens, 4 parameters on every screen, as Figure 8-10 to Figure 8-12 show. The saved QC results are sequentially displayed in the L-J graph, the latest on the utmost left (No.1).

The L-J graph can be interpreted as follows:

- The x-coordinate represents the number of the L-J analyses performed; the y-coordinate represents the results of the L-J analyses.
- For every parameter, its L-J graph can display maximum 31 points.
- For every parameter, the upper dash line represents the expected result + limit.
- For every parameter, the lower dash line represents the expected result – limit.
- For every parameter(e.g. WBC), the three numbers to the left of the graph are:

10.4 – the expected result ＋ limit;
9.9 – the expected result;
9.4 – the expected result – limit.

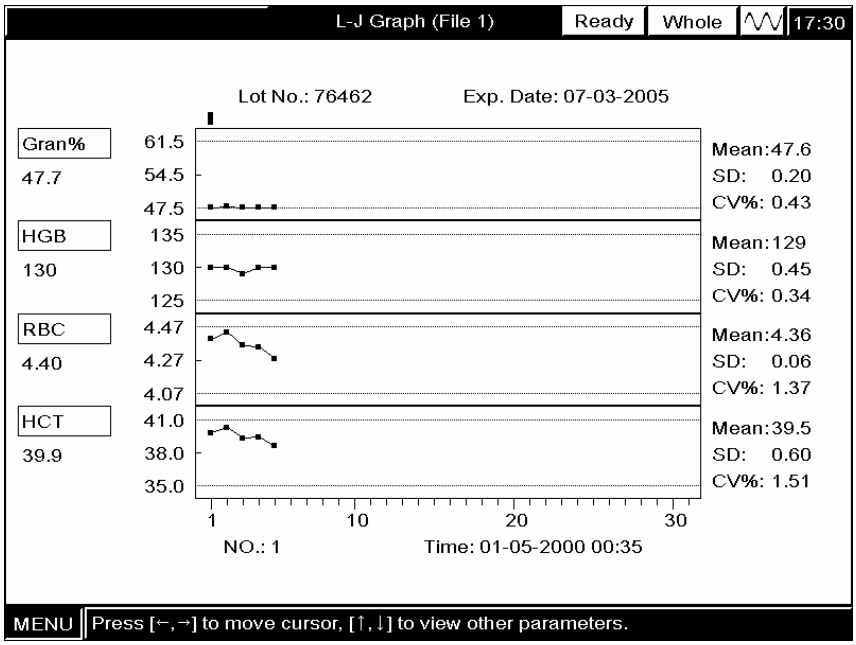


Figure 8-11"L-J Graph"screen 2

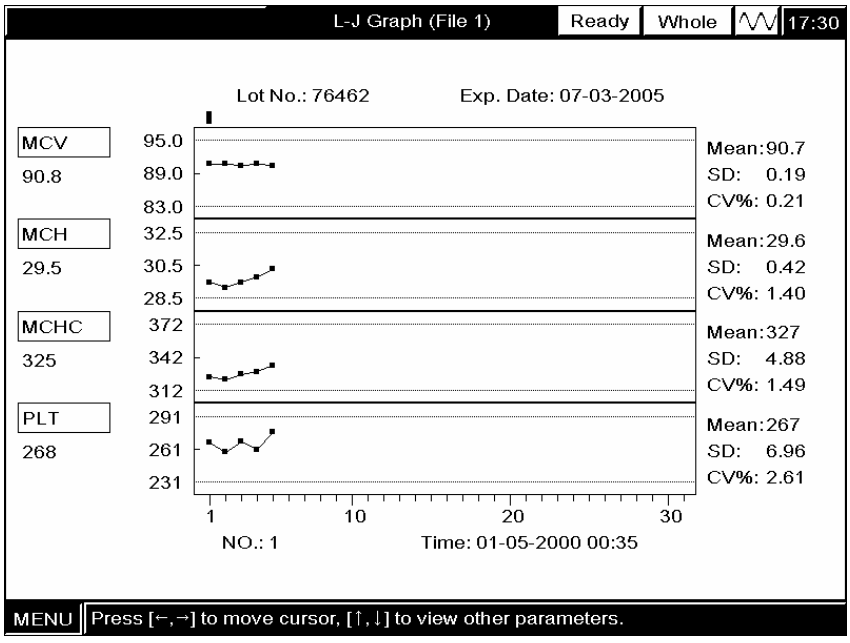


Figure 8-12"L-J Graph"screen 3

For every parameter，the three numbers to the right of the L-J graph are defined and calculated as follows:

Mean – the average of the saved QC runs;

SD – Standard Deviation;

CV% – Coefficient of Variation.

$$\text{Mean} = \frac{\sum_{i=1}^{n} X_i}{n}$$

$$SD = \sqrt{\frac{\sum (X_i - \text{Mean})^2}{n-1}}$$

$$CV\% = \frac{SD}{\text{Mean}} \times 100$$

Where, n is the number of the saved L-J analyses and X_i is the result of the i^{th} L-J analysis.

If the saved L-J analyses are less than 3, only the "**mean**" will be displayed. For a parameter, if any of the saved results is non-numeric (*), the "**mean**", "**SD**" and "**CV%**" are all empty.

The "■" and "□"points in the graphs can be interpreted as follows:
The "■" points fallen between the upper and lower dash lines are within the expected ranges;
The "■"points fallen outside the upper and lower dash lines are out of the expected ranges
The "□" points represents non-numeric parameter values (*), which can be caused by either errors during the run or values outside the operating range.

If you see any points fallen outside the control range, do the following steps until the problem is solved. If all the steps have failed, contanct Mindray customer service department or your local distributor for assistance.

1. Check the upper left corner of the screen for error messages. Refer to **Chapter 11 Troubleshooting Your Analyzer** for solutions to any displayed error messages;
2. Check the L-J settings for inappropriate entries;
3. Do the background check. In case of an abnormal background result, refer to **Chapter 11 Troubleshooting Your Analyzer** for solutions;
4. Re-run the control;
5. Run another vial of control;
6. Check if the analyzer needs to be calibrated.

- Browsing results of L-J analyses

Press [↑] or [↓] to review the preceding or following screen; press [←] or [→] to review the preceding or following result. The parameter value of the current point (the one the cursor is located at) is displayed below the parameter box. The location of the current point is displayed in the "**No.**" field. The analysis time is displayed in the "**Time**" field.

- Printing L-J graphs

Press [PRINT] to print out the displayed L-J graphs.

- Exiting the "**L-J Graph**" screen

Press [MENU] to exit to the system menu, or press [MAIN] to exit to the "**Count**" screen.

"L-J Table" mode

- Entering the "**L-J Table**"screen

Press [MENU] to enter the system menu.

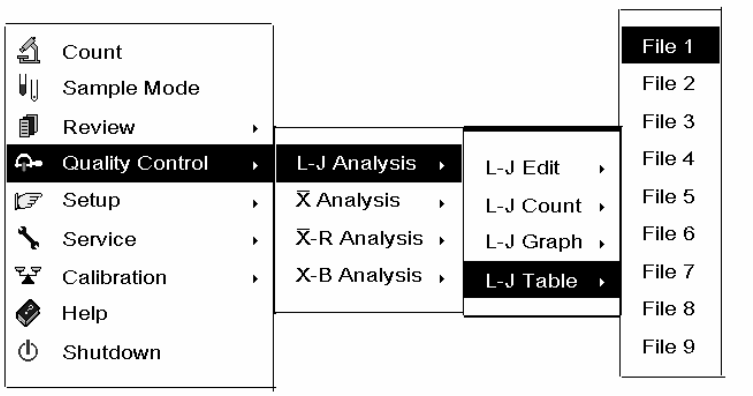
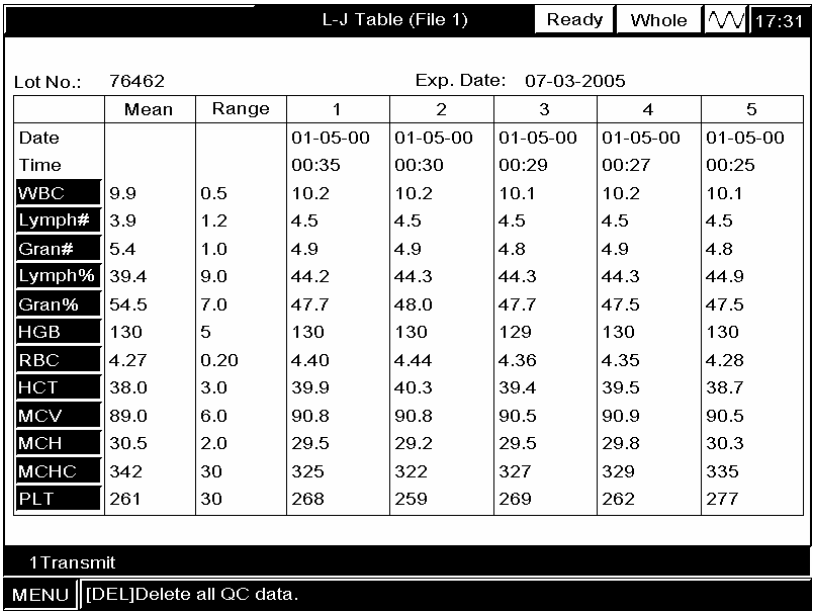


Figure8-13 System menu

SELECT "**Quality Control → L-J Analysis →L-J Table → File 1**" (Figure8-13) to enter the "**L-J Table**" screen (Figure 8-14). Every screen displays 5 results. The parameter values fallen outside the expected range will be flagged "H" (higher than the upper limit) or "L" (lower than the lower limit).



	Mean	Range	1	2	3	4	5
Date			01-05-00	01-05-00	01-05-00	01-05-00	01-05-00
Time			00:35	00:30	00:29	00:27	00:25
WBC	9.9	0.5	10.2	10.2	10.1	10.2	10.1
Lymph#	3.9	1.2	4.5	4.5	4.5	4.5	4.5
Gran#	5.4	1.0	4.9	4.9	4.8	4.9	4.8
Lymph%	39.4	9.0	44.2	44.3	44.3	44.3	44.9
Gran%	54.5	7.0	47.7	48.0	47.7	47.5	47.5
HGB	130	5	130	130	129	130	130
RBC	4.27	0.20	4.40	4.44	4.36	4.35	4.28
HCT	38.0	3.0	39.9	40.3	39.4	39.5	38.7
MCV	89.0	6.0	90.8	90.8	90.5	90.9	90.5
MCH	30.5	2.0	29.5	29.2	29.5	29.8	30.3
MCHC	342	30	325	322	327	329	335
PLT	261	30	268	259	269	262	277

Figure 8-14 "L-J Table"screen

- Browsing results of L-J analyses

Press [PgUp] or [PgDn] to review the preceding or following screen.

- Deleting results of L-J analyses

Press [DLE] and a message box will pop up to ask you whether to delete all the QC results saved in this file, as Figure8-15 shows. ***CLICK*** "**Enter**" to confirm the deletion; ***CLICK*** "**Cancel**"to abort the deletion.

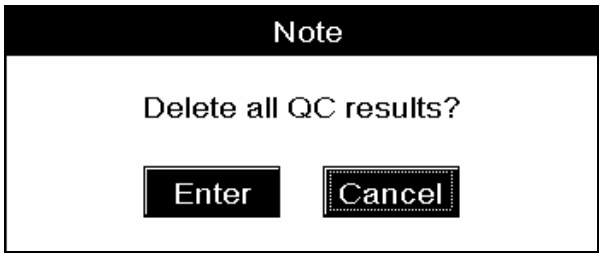


Figure8-15 A message box to confirm the deletion

- Transmitting results of L-J analyses to a host

If you want to transmit all the L-J analysis results to an external computer (a host), press [1] and a message box will pop up to confirm the transmission, as Figure8-16 shows. ***CLICK*** "**Enter**" to confirm the transmission； ***CLICK*** "**Cancel**" to abort the transmission.

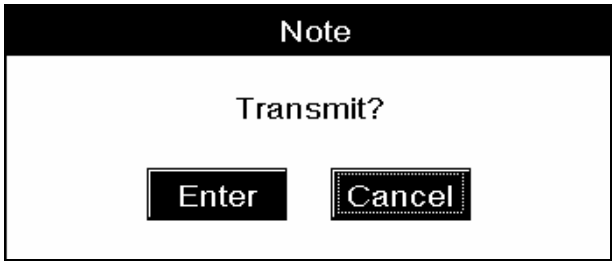


Figure8-16 A message box to confirm the transmission

- Printing results of L-J analyses

Press [PRINT] to print out all the L-J analysis results.

- Exiting the "**L-J Table**" screen

Press [MENU] to exit to the system menu, or press [MAIN] to exit to the "**Count**" screen.

8.3 "$\overline{X}$ Analysis" Program

Using the "$\overline{X}$ **Analysis**" program, you can provide quality control for maximum 12 parameters. The analyzer provides 9 QC files for you to save QC settings and results. Every QC file can save maximum 31 QC run results. When the saved QC results have reached the maximum number, the newest result will overwrite the oldest. The following introduction will use "**File 1**" as the example.

8.3.1 Editing $\overline{X}$ Analysis Settings

- Entering the "$\overline{X}$ **Edit**" screen

Press [MENU] to enter the system menu.

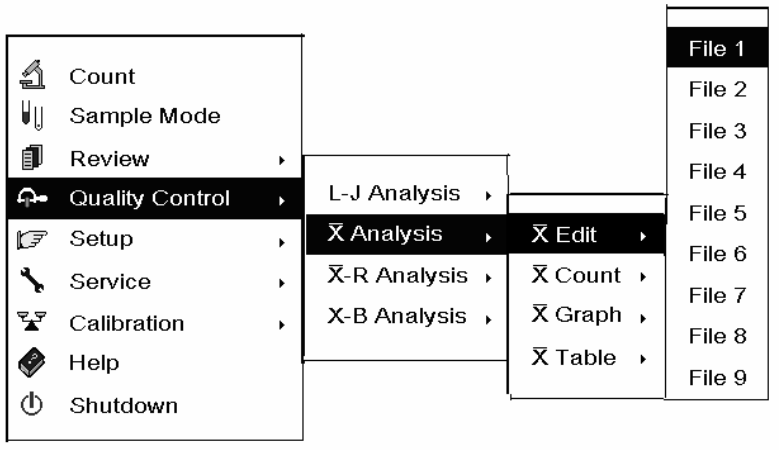


Figure8-17 System menu

SELECT "**Quality Control** → $\overline{X}$ **Analysis** →$\overline{X}$ **Edit** → **File 1**"（Figure8-17）to enter the "$\overline{X}$ **Edit**" screen (Figure 8-18).

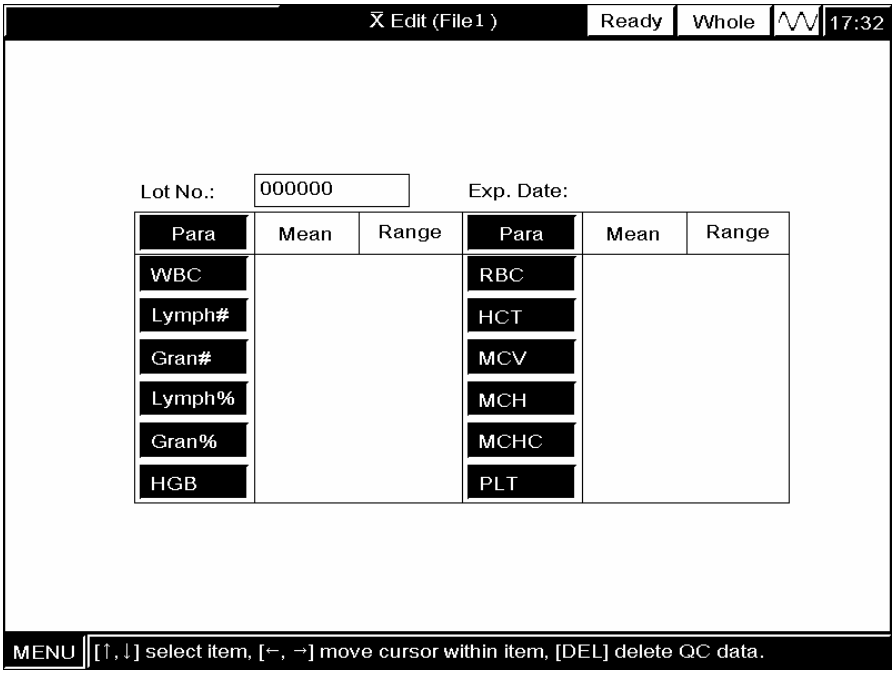


Figure 8-18 "$\bar{X}$ Edit" screen

If there are saved $\bar{X}$ analysis results and settings, you need to delete them first. Press [DEL] and a message box will pop up to confirm the deletion, as shows Figure8-19 shows.

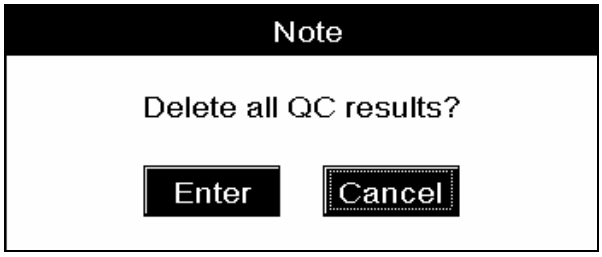


Figure8-19 A message box to confirm the deletion

***CLICK* "Enter"** to confirm the deletion; ***CLICK* "Cancel"**to abort the deletion.

- Entering lot number

ENTER the lot number of the control to be used into the "**Lot No.**" box.

- Entering Exp. Date

ENTER the expiration date of the control to be used into the "**Exp. Date**" box.

- Entering the expected results (mean) and limits (range)

ENTER the expected results (mean) and limits (range) respectively into the "**Mean**" box and "**Range**" boxes of the parameters to be included in the $\bar{X}$ analysis.

NOTE

- **Refer to the instructions of use of the control for information on the lot number, expiration date, open-vial stability days, expected results and limits.**
- **The entered expiration date should be either the expiration date printed on the labeling or the open-vial expiration date, whichever is earlier.**
- **The open-vial expiration date is calculated as follows: the date that vial is opened + the open-vial stability days.**
- **At the "$\bar{X}$ Edit" screen, if you want to correct an erroneous entry, *MODIFY* the wrong digit.**

■ Deleting settings

Press [DEL] to delete all the settings.

■ Printing settings

Press [Print] to print out all the settings.

■ Exiting the "$\bar{X}$ **Edit**" screen

Press [MENU] to exit to the system menu, or press [MAIN] to exit to the "**Count**" screen.

A message box shown in Figure8-20 will pop up, if :
There is a parameter for which you have entered only the expected result or the limit;
or
There is a parameter whose expected result is less than or equal to the limit.

CLICK "**Enter**" to close the box and clear the erroneous entries. Re-enter the correct values before trying to exit the screen again.

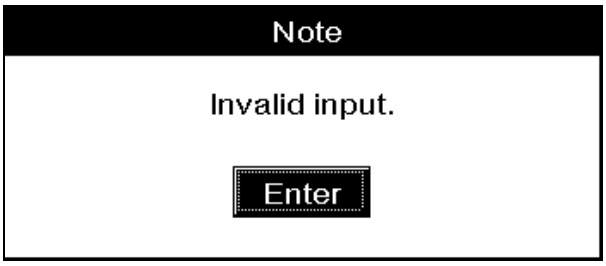


Figure8-20An "Invalid input"message box

In case of any invalid entries of expiration dates, a message box will pop up to remind you of the error, as Figure8-21shows. ***CLICK*** "**Enter**" to close the box and clear the erroneous entries. Re-enter the correct values before trying to exit the screen again. The settings can be

saved only when both the expected result and limit are valid.

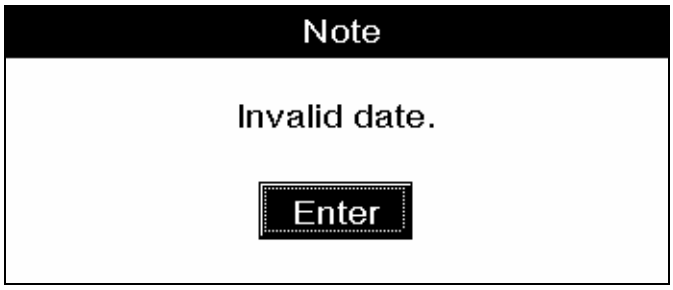


Figure8-21 An"Invalid date"message box

If all the entries are correct, a message box will pop up to remind you to save the changes, as Figure 8-22 shows. ***CLICK*** "**Enter**" to save the changes and exit to the system menu (or the **"Count"** screen); ***CLICK*** "**Cancel**" to abort the changes and exit to the system menu (or the "**Count**" screen).

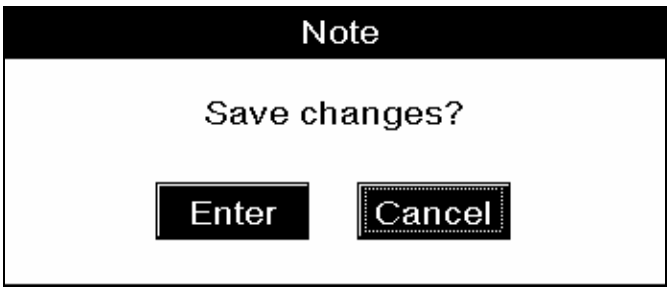


Figure 8-22 A message box to confirm the changes

8.3.2 Running the Controls

- Selecting Whole Blood mode

Press [MENU] and ***SELECT*** "**Mode**" to enter the "**Mode**"screen. ***SELECT*** "**Whole Blood**" ***from the"*****Sample Mode*****" pull-down list***.

- Entering the "$\overline{X}$ **Count**" screen

Press [MENU] to enter the system menu. ***SELECT*** "**Quality Control** → $\overline{X}$ **Analysis** → $\overline{X}$ **Count** → **File 1**" to enter the "$\overline{X}$ **Count**"screen, as Figure8-23 shows.

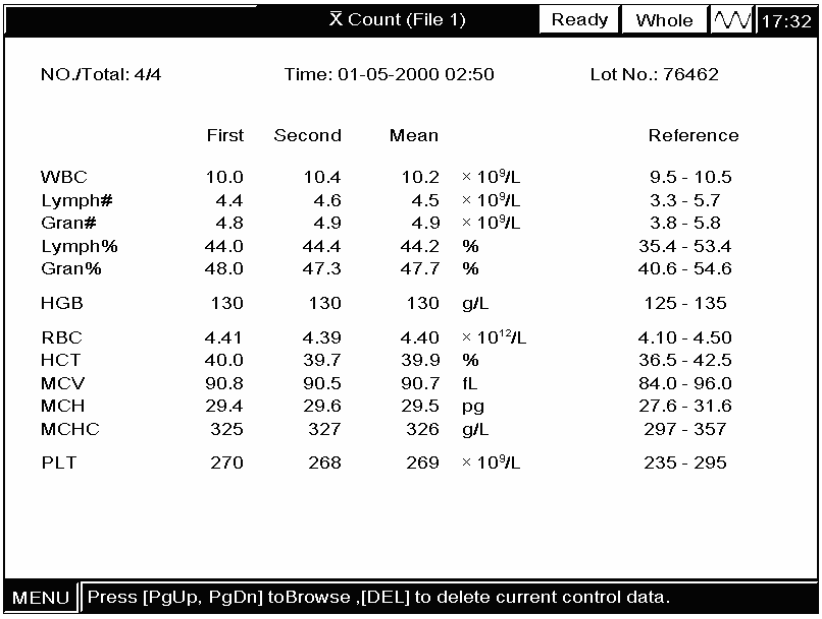


Figure8-23 "$\bar{X}$ Count"screen

NOTE

- **Be sure to use the Mindray - specified controls. Using controls other than the specified will lead to misleading results.**
- **Refer to the instructions of use of the controls for how to store and use the controls.**

- **Samples, controls, calibrators and waste are potentially infectious. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them in the laboratory.**

⚠ WARNING

- **The sample probe tip is sharp and may contain biohazardous materials. Exercise caution to avoid contact with the probe when working around it.**
- **Do not re-use such disposable product as collection tubes, test tubes, capillary tubes, etc.**

NOTE

- **When switching from the Predilute mode to the Whole Blood mode, the analyzer will automatically flush the fluidic system.**
- **Be sure to keep the sample probe tip away from the tube bottom, otherwise the aspiration volume may be inaccurate.**
- **When the aspiration is done, remove the sample tube only when the sample probe is out of the tube.**

■ Running the controls

1. Be sure the **System Status** area displays "**Ready**" and **Count Mode** area displays "**Whole**";
2. Present a vial of control to the sample probe so that the tip is well into the vial, and press the aspirate key. The **System Status** area will display "**Running**" and the analyzer will start aspirating control;
3. When you hear the beep and the sample probe is out of the vial, remove the control vial. The sample probe will retract into the analyzer and the analysis progress will be displayed on the screen;
4. When the analysis is finished, the sample probe is replaced, the analysis result is displayed on the screen, and a message box pops up to confirm the validity of the analysis result, as Figure8-24 shows;

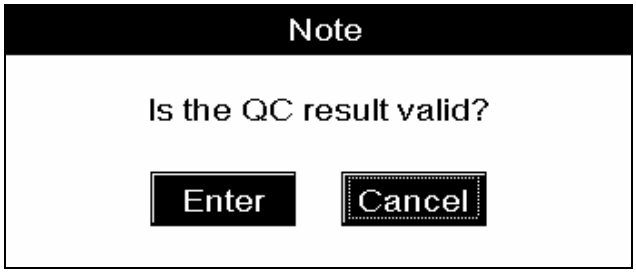


Figure8-24 A message to confirm the validity

5. ***CLICK*** "**Enter**" to save the result and the "**NO./Total**" in the upper left corner of the screen will automatically increase by 1; ***CLICK*** "**Cancel**" to abort the result;
6. Follow the above steps to have another QC run. When you have obtained two valid QC results, the analyzer will calculate the average and take it as an $\overline{X}$ analysis result. The average will be flagged "H" or "L" if it falls outside the expected range.

NOTE

- **If the analyzer detects WBC/RBC clogging or bubbles during the analysis, the corresponding error messages will be displayed in the upper left corner of the screen and the results of all the related parameters will be invalidated. See Chapter 11 Troubleshooting for solutions.**
- **If the ambient temperature is outside the specified operating range, the analyzer will alarm you for abnormal ambient temperature and the analysis results may be unreliable. See Chapter 11 Troubleshooting for solutions.**

■ Browsing results of other $\overline{X}$ analyses

To browse the result of the preceding or following $\overline{X}$ analyses, press [PgUp] or [PgDn].

■ Deleting results $\overline{X}$ analyses

To delete the current result, press [DEL] and a message box will pop up, as Figure 8-25 shows. ***CLICK*** "**Enter**" to confirm the deletion; ***CLICK*** "**Cancel**" to abort the deletion.

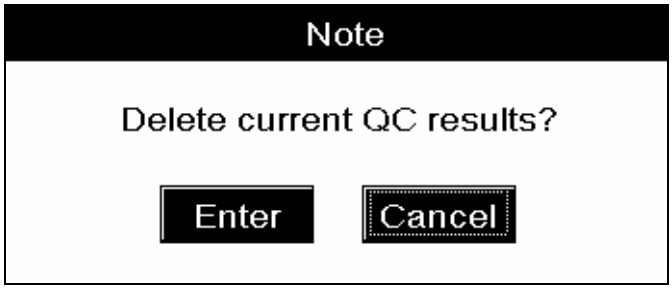


Figure 8-25 A message box to confirm the deletion

■ Printing $\overline{X}$ analysis results

Press [PRINT] to print out the current $\overline{X}$ analysis result by the printer.

■ Exiting the "$\overline{X}$ **Count**" screen

Press [MENU] to exit to the system menu, or press [MAIN] to exit to the "**Count**" screen.

8.3.3 Reviewing $\bar{X}$ Analysis Results

You can review the $\bar{X}$ analysis results in either the "$\bar{X}$ **Graph**" mode or "$\bar{X}$ **Table**" mode.

"$\bar{X}$ Graph" mode

- Entering the "$\bar{X}$ **Graph**" screen

Press [MENU] to enter the system menu.

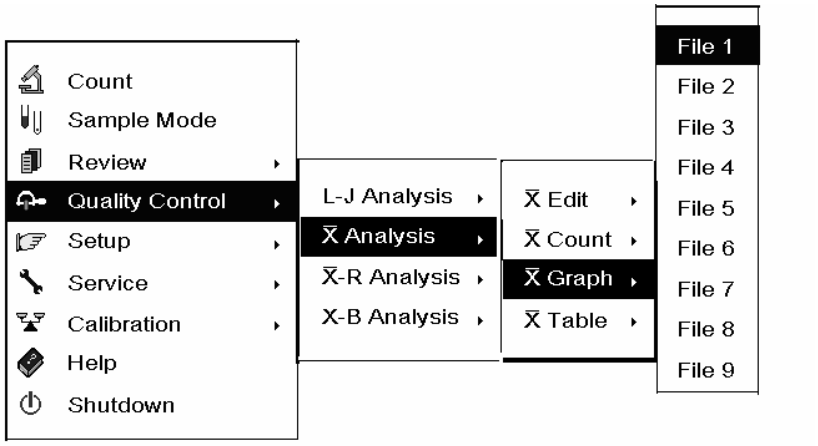


Figure8-26 System menu

SELECT "**Quality Control→$\bar{X}$ Analysis →$\bar{X}$ Graph → File 1**"(Figure8-26) to enter the "$\bar{X}$ **Graph**" screen (Figure8-27).

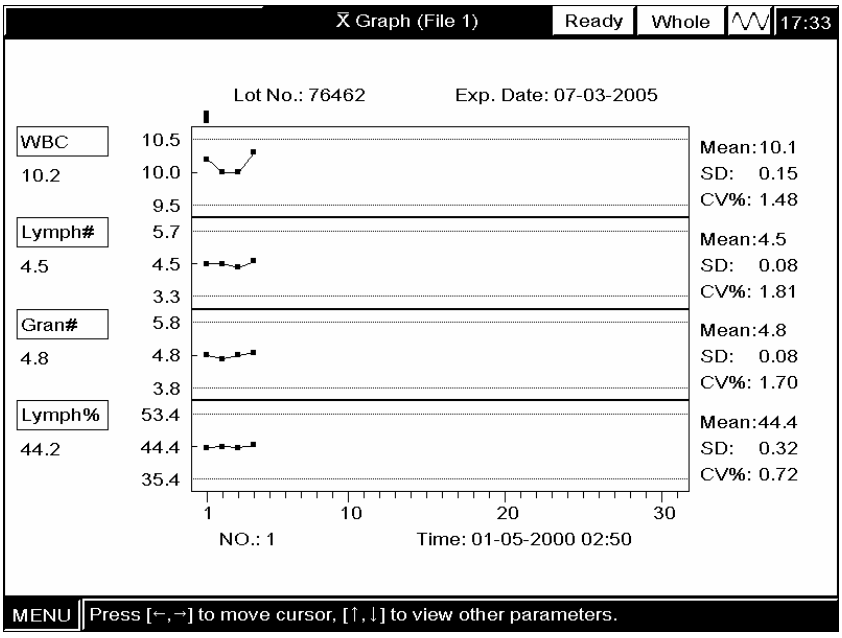


Figure8-27"$\bar{X}$ Graph"screen

The 12 parameters are displayed on three screens, 4 parameters on every screen, as Figure8-27 to Figure 8-29 show. The saved $\overline{X}$ analysis results are sequentially displayed in the $\overline{X}$ graph, the latest on the utmost left (No.1).

The $\overline{X}$ graph can be interpreted as follows:

- The x-coordinate represents the number of the $\overline{X}$ analyses performed; the y-coordinate represents the results of the $\overline{X}$ analyses;
- For every parameter, its $\overline{X}$ graph can display maximum 31 points;
- For every parameter, the upper dash line represents the expected result + limit;
- For every parameter, the lower dash line represents the expected result – limit;
- For every parameter(e.g. WBC), the three numbers to the left of the graph are:

10.5 – the expected result ＋ limit;
10.0 – the expected result;
9.5 – the expected result – limit.

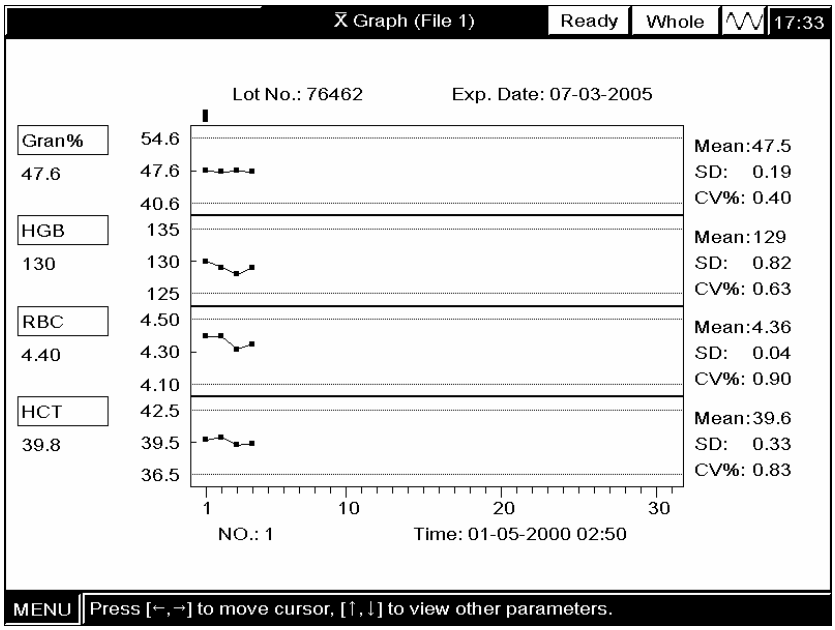


Figure 8-28 "$\overline{X}$ Graph"screen 2

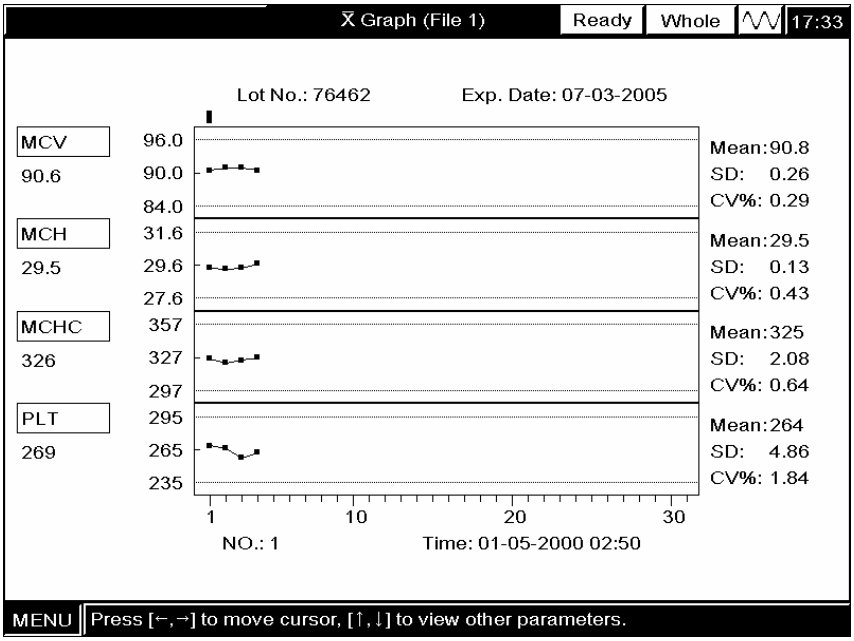


Figure 8-29 "$\bar{X}$ Graph"screen 3

For every parameter，the three numbers to the right of the $\bar{X}$ graph are defined and calculated as follows:

Mean – the average of the saved $\bar{X}$ analyses;

SD – Standard Deviation;

CV% – Coefficient of Variation.

$$\text{Mean} = \frac{\sum_{i=1}^{n} X_i}{n}$$

$$SD = \sqrt{\frac{\sum (X_i - \text{Mean})^2}{n-1}}$$

$$CV\% = \frac{SD}{\text{Mean}} \times 100$$

Where, n is the number of the $\bar{X}$ analyses performed and X_i is the result of the i^{th} $\bar{X}$ analysis.

If the saved $\bar{X}$ analyses are less than 3, only the "**mean**" will be displayed. For a parameter, if any of the saved results is non-numeric *, the "**mean**", "**SD**" and "**CV%**" are all empty.

The "■" and "□"points in the graphs can be interpreted as follows:

The "■"points fallen between the upper and lower dash lines are within the expected ranges;

The "■"points fallen outside the upper and lower dash lines are out of the expected ranges ;

The "□" points represents non-numeric parameter values (*).

If you see any points fallen outside the control range, do the following steps until the problem is solved. If all the steps have failed, contact Mindray customer service departmentor your local distributor for assistance.

1. Check the upper left corner of the screen for error messages. Refer to **Chapter 11 Troubleshooting Your Analyzer** for solutions to any displayed error messages;
2. Check the $\bar{X}$ settings for inappropriate entries;
3. Do the background check. In case of an abnormal background result, refer to **Chapter 11 Troubleshooting Your Analyzer** for solutions;
4. Re-run the control;
5. Run another vial of control;
6. Check if the analyzer needs to be calibrated.

■ Browsing results of $\bar{X}$ analyses

Press [↑] or [↓]to review the preceding or following screen; press[←] or [→] to review the preceding or following result. The parameter value of the current point (the one the cursor is located at) is displayed below the parameter box. The location of the current point is displayed in the "**No.**" field. The analysis time is displayed in the "**Time**" field.

■ Printing $\bar{X}$ graphs

Press [PRINT] to print out the displayed $\bar{X}$ graphs.

■ Exiting the "$\bar{X}$ Graph" screen

Press [MENU] to exit to the system menu, or press [MAIN] to exit to the "**Count**" screen.

"$\bar{X}$ Table" mode

■ Entering the "$\bar{X}$ **Table**"mode

Press [MENU] to enter the system menu.

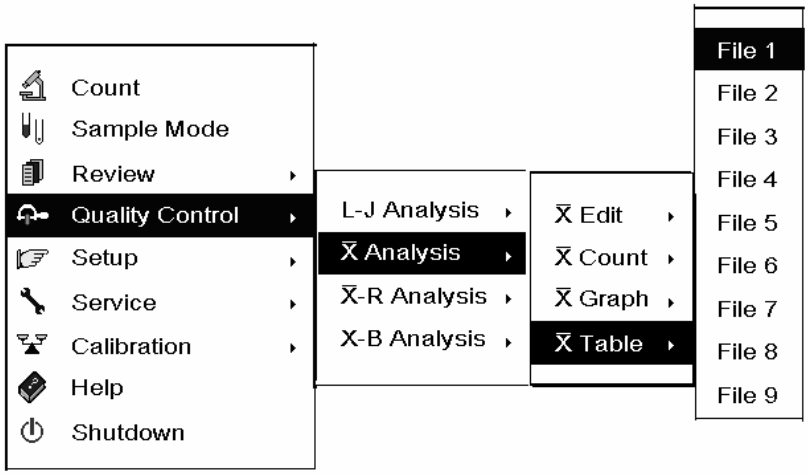


Figure 8-30 System menu

SELECT "**Quality Control →Analysis →Table→ File 1**" (Figure 8-30) to enter the "$\overline{X}$ **Table**" screen (Figure8-31). Every screen displays 5 results. The parameter value fallen outside the expected range will be flagged "H" (higher than the upper limit) or "L" (lower than the lower limit).

X̄ Table (File 1) | Ready | Whole | 17:34

Lot No.: 76462 Exp. Date: 07-03-2005

	Mean	Range	1	2	3	4	5
Date			01-05-00	01-05-00	01-05-00	01-05-00	
Time			02:50	02:47	02:44	02:40	
WBC	10.0	0.5	10.2	10.0	10.0	10.3	
Lymph#	4.5	1.2	4.5	4.5	4.4	4.6	
Gran#	4.8	1.0	4.8	4.7	4.8	4.9	
Lymph%	44.4	9.0	44.2	44.7	44.2	44.8	
Gran%	47.6	7.0	47.6	47.4	47.8	47.4	
HGB	130	5	130	129	128	129	
RBC	4.30	0.20	4.40	4.40	4.32	4.35	
HCT	39.5	3.0	39.8	40.0	39.3	39.4	
MCV	90.0	6.0	90.6	91.1	91.1	90.7	
MCH	29.6	2.0	29.5	29.4	29.5	29.7	
MCHC	327	30	326	323	325	328	
PLT	265	30	269	267	258	263	

MENU | [DEL]Delete all QC data.

Figure8-31"$\overline{X}$ Table"screen

- Browsing $\overline{X}$ analysis results

Press [PgUp] or [PgDn] to review the preceding or following screen.

- Deleting QC results

Press [DLE] and a message box will pop up to ask you whether to delete all the QC results

saved in this file, as Figure8-32 shows. ***CLICK*** "**Enter**" to confirm the deletion; ***CLICK*** "**Cancel**" to abort the deletion.

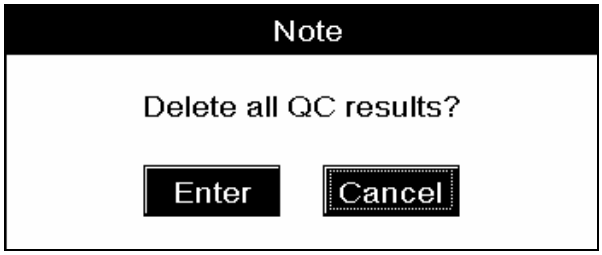


Figure8-32 A message box to confirm the deletion

- Printing QC results

Press [PRINT] to print out all the QC results saved in this file.

- Exiting the "$\overline{X}$ **Table**" screen

Press [MENU] to exit to the system menu; press [MAIN] to exit to the "**Count**" screen.

8.4 "$\overline{X}$-R Analysis" program

Using the "$\overline{X}$**-R Analysis**" program, you can provide quality control for maximum 12 parameters. The analyzer provides 9 QC files for you to save QC settings and results. Every QC file can save maximum 31 QC run results. When the saved QC results have reached the maximum number, the newest result will overwrite the oldest. The following introduction will use "**File 1**" as the example.

8.4.1 Editing $\overline{X}$-R Analysis Settings

- Entering the "$\overline{X}$-R **Edit**" screen

Press [MENU] to enter the system menu.

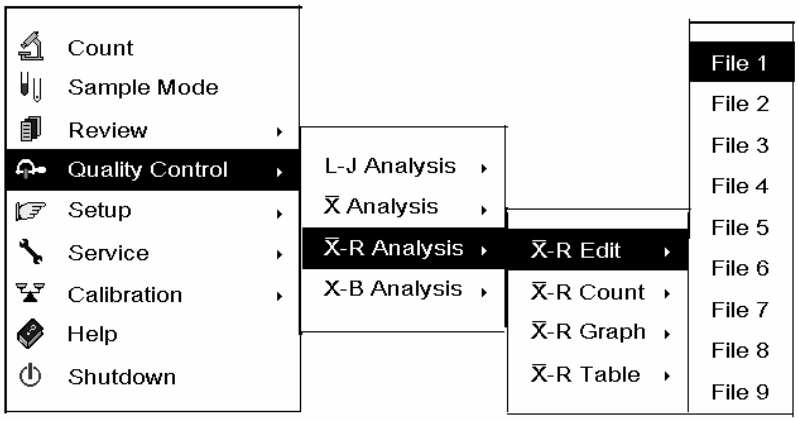


Figure8-33 System menu

SELECT "**Quality Control** → $\overline{X}$-R **Analysis** → $\overline{X}$-R **Edit** → **File 1**" （Figure8-33）to enter the "$\overline{X}$-R **Edit**" screen (Figure8-34).

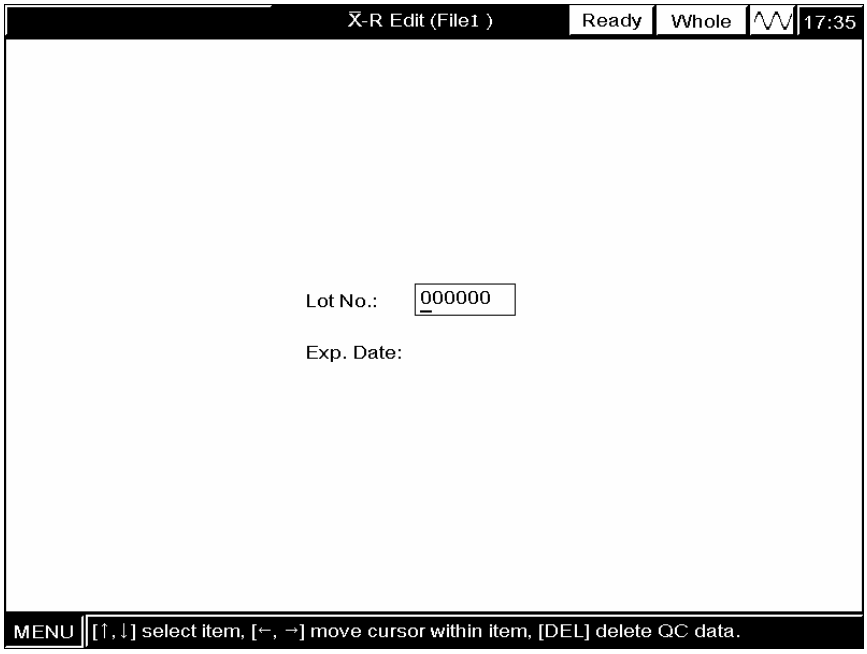


Figure8-34 "$\bar{X}$-R Edit" screen

If there are saved QC results and settings, you need to delete them first. Press [DEL] and a message box will pop up to confirm the deletion, as Figure8-35 shows.

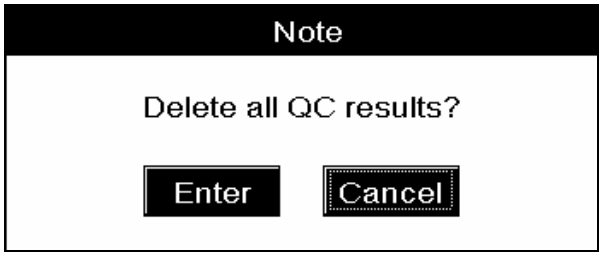


Figure8-35 A message box to confirm the deletion

CLICK "**Enter**" to confirm the deletion; ***CLICK*** "**Cancel**" to abort the deletion.

- Entering lot number

ENTER the lot number of the control to be used into the "**Lot No.**" box.

- Entering Exp. Date

ENTER the expiration date of the control to be used into the "**Exp. Date**" box.

NOTE

- **Refer to the instructions of use of the control for information on the lot number, expiration date, open-vial stability days, expected results and limits.**
- **The entered expiration date should be either the expiration date printed on the labeling or the open-vial expiration date, whichever is earlier.**
- **The open-vial expiration date is calculated as follows: the date that vial is opened + the open-vial stability days.**
- **At the "$\overline{X}$-R Edit" screen, if you want to correct an erroneous entry, *MODIFY* the wrong digit.**

■ Deleting settings

Press [DEL] to delete all the settings.

■ Exiting the "$\overline{X}$-R **Edit**" screen

Press [MENU] to exit to the system menu, or press [MAIN] to exit to the "**Count**" screen.
In case of an invalid entry of expiration date, a message box will pop up to remind you of the error, as Figure8-36 shows. ***CLICK*** "**Enter**" to close the box and clear the erroneous entries. Re-enter the correct values before trying to exit the screen again.

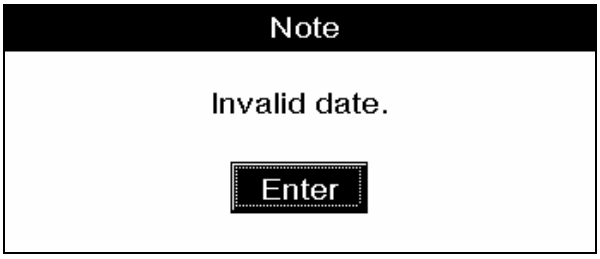


Figure8-36 An"Invalid date"message box

If all the entries are correct, a message box will pop up to remind you to save the changes, as Figure 8-37shows. ***CLICK*** "**Enter**" to save the changes and exit to the system menu (or the "**Count**" screen); ***CLICK*** "**Cancel**" to abort the changes and exit to the system menu (or the "**Count**" screen).

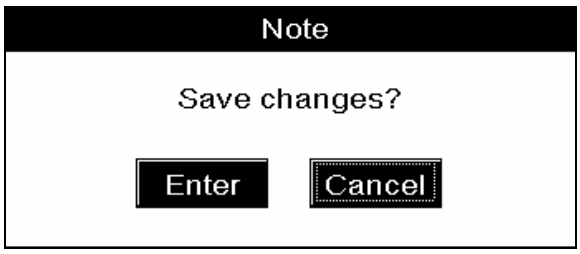


Figure 8-37 A message box to confirm the changes

8.4.2 Running the Controls

- Selecting Whole Blood mode

Press [MENU] and ***SELECT*** "**Mode**" to enter the "**Mode**"screen. ***SELECT*** "**Whole Blood**" ***from the "*****Sample Mode*****" pull-down list***.

- Entering the "$\bar{X}$**-R Count**" screen

Press [MENU] to enter the system menu. ***SELECT*** "**Quality Control →** $\bar{X}$-R **Analysis→**$\bar{X}$-R **Count → File 1**" to enter the "$\bar{X}$**-R Count**" screen (Figure8-38).

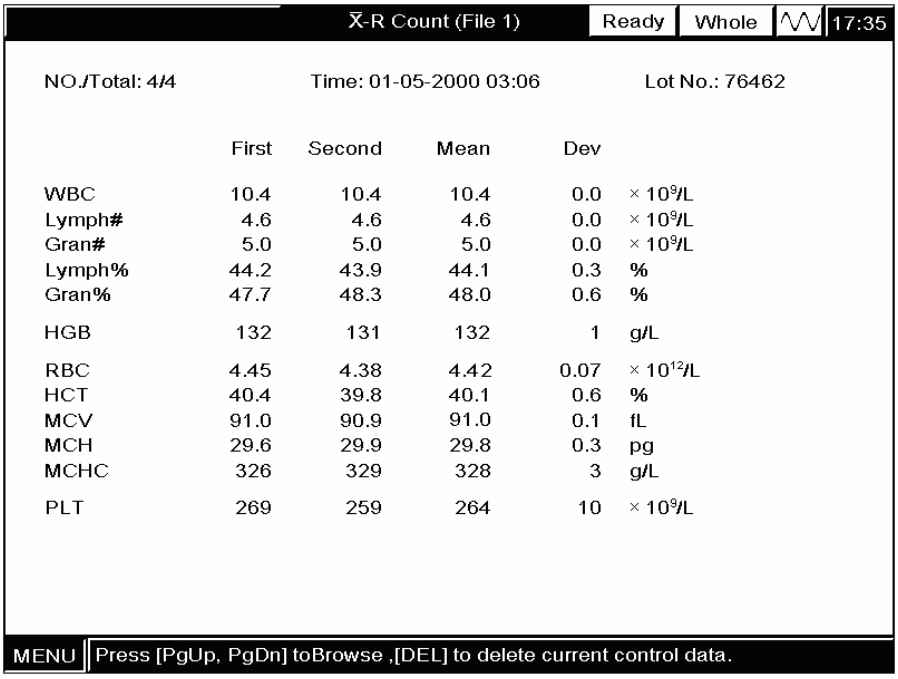


Figure8-38 "$\bar{X}$-R Count"screen

NOTE

- **Be sure to use the Mindray - specified controls. Using controls other than the specified will lead to misleading results.**
- **Refer to the instructions of use of the controls for how to store and use the controls.**

- **Samples, controls, calibrators and waste are potentially infectious. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them in the laboratory.**

⚠ WARNING

- **The sample probe tip is sharp and may contain biohazardous materials. Exercise caution to avoid contact with the probe when working around it.**
- **Do not re-use such disposable product as collection tubes, test tubes, capillary tubes, etc.**

NOTE

- **When switching from the Predilute mode to the Whole Blood mode, the analyzer will automatically flush the fluidic system.**
- **Be sure to keep the sample probe tip away from the tube bottom, otherwise the aspiration volume may be inaccurate.**
- **When the aspiration is done, remove the sample tube only when the sample probe is out of the tube.**

■ Running the controls

1. Be sure the **System Status** area displays "**Ready**" and **Count Mode** area displays "**Whole**";
2. Present a vial of control to the sample probe so that the tip is well into the vial, and press the aspirate key. The **System Status** area will display "**Running**" and the analyzer will start aspirating sample;
3. When you hear the beep and the sample probe is out of the vial, remove the control vial. The sample probe will retract into the analyzer and the analysis progress will be displayed on the screen;
4. When the analysis is finished, the sample probe is replaced, the analysis result is displayed on the screen, and a message box pops up to confirm the validity of the analysis results, as Figure8-39 shows;

5. ***CLICK*** "**Enter**" to save the result and the "**NO./Total**" in the upper left corner of the screen will automatically increase by 1; ***CLICK*** "**Cancel**" to abort the result;

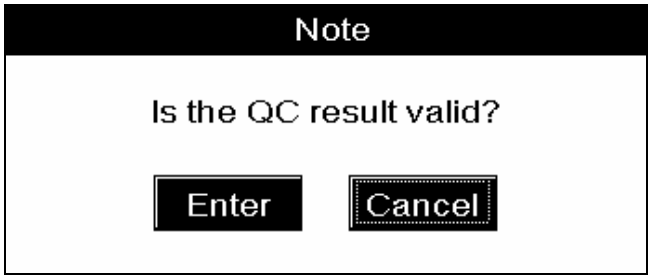


Figure8-39 A message to confirm the validity of the QC run

6. Follow the above steps to run the control again. When you have obtained two valid QC results, the analyzer will calculate the average $\overline{X}$ and the difference R. The calculated $\overline{X}$ and R will be respectively displayed on the screen.

NOTE

- **If the analyzer detects WBC/RBC clogging or bubbles during the analysis, the corresponding error messages will be displayed in the upper left corner of the screen and the results of all the related parameters will be invalidated. See Chapter 11 Troubleshooting for solutions.**
- **If the ambient temperature is outside the specified operating range, the analyzer will alarm you for abnormal ambient temperature and the analysis results may be unreliable. See Chapter 11 Troubleshooting for solutions.**

■ Browsing results of other $\overline{X}$-R analyses

Press [PgUp] or [PgDn] to browse the result of the preceding or following $\overline{X}$-R analysis.

■ Deleting results of $\overline{X}$-R analyses

To delete the current $\overline{X}$-R analysis result, press [DEL] and a message box will pop up, as Figure8-40 shows. ***CLCIK*** "**Enter**" to confirm the deletion; ***CLICK*** "**Cancel**" to abort the deletion.

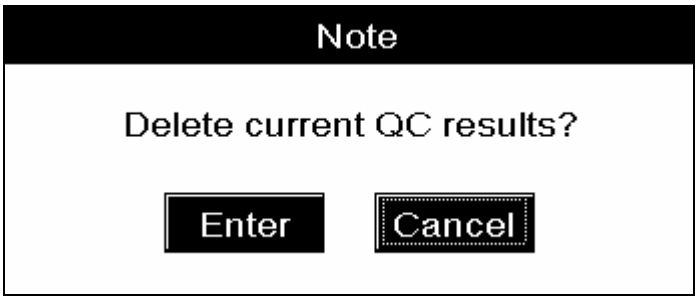


Figure8-40 A message box to confirm the deletion

- Printing results of $\bar{X}$-R analyses

Press [PRINT] to print out the current $\bar{X}$-R analysis result by the printer.

- Exiting the "$\bar{X}$-R **Count**" screen

Press [MENU] to exit to the system menu, or press [MAIN] to exit to the "**Count**" screen.

8.4.3 Reviewing the $\bar{X}$-R Analysis Results

You can review the $\bar{X}$－R analysis results in either the "$\bar{X}$-R **Graph**" mode or "$\bar{X}$-R **Table**" mode.

"$\bar{X}$-R Graph" mode

- Entering the "$\bar{X}$**-R Graph**" screen

Press [MENU] to enter the system menu.

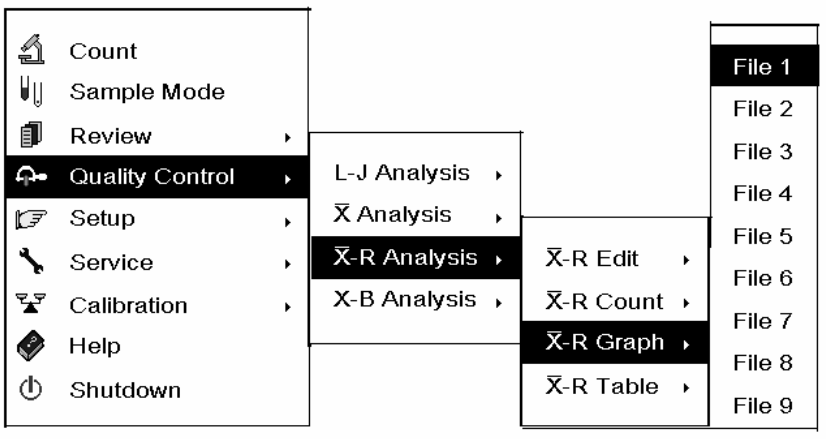


Figure 8-41 System menu

SELECT "**Quality Control** → $\bar{X}$-R **Analysis** → $\bar{X}$-R **Graph** → **File 1**" (Figure 8-41) to enter the "$\bar{X}$**-R Graph**" screen (Figure8-42).

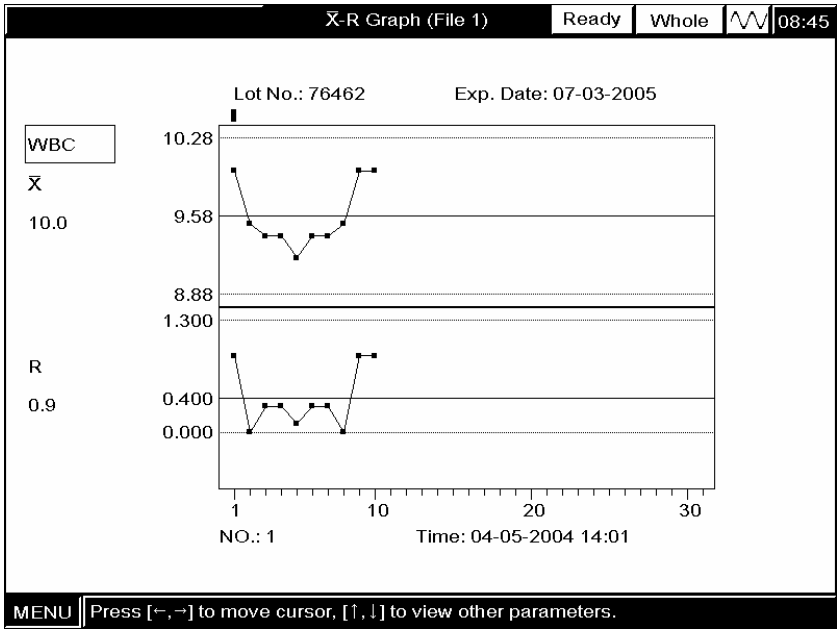


Figure8-42"$\overline{X}$－R Graph"screen

Every screen displays the $\overline{X}$ and R graphs of one parameter.

The $\overline{X}$ graph can be interpreted as follows:

- The x-coordinate represents the number of the $\overline{X}$-R analyses performed; the y-coordinate represents the results of the $\overline{X}$-R analyses;
- For every parameter, its $\overline{X}$ graph can display maximum 31 points;
- For every parameter, the center dash line represents the $\overline{X}$ （average of all the $\overline{X}$-R analyses performed);
- For every parameter, the upper dash line represents the upper control limit = $\overline{X}+A\times\overline{R}$;
- For every parameter, the lower dash line represents the upper control limit = $\overline{X}-A\times\overline{R}$;
- For every parameter(e.g. WBC), the three numbers to the left of the graph are:

10.2 – $\overline{X}+A\times\overline{R}$;
10.1 – $\overline{X}$;
10.0 – $\overline{X}-A\times\overline{R}$.

The R graph can be interpreted as follows:

- The x-coordinate represents the number of the $\overline{X}$ － R analyses performed; the y-coordinate represents the difference between the two runs of every $\overline{X}$－R analysis;
- For every parameter，its R graph displays maximum 31 points;
- For every parameter，the center line of its R-graph represents the average of all the differences $\overline{R}$;
- For every parameter，the upper dash line represents the upper control limit B× $\overline{R}$;

■ For every parameter，the lower dash line represents the lower control limit of the expected range C× $\overline{R}$;

■ For every parameter(e.g. WBC) the three numbers to the left of its R graph are defined as follows:

0.3 – B× $\overline{R}$;
0.1 – $\overline{R}$;
0.0 – C× $\overline{R}$.

Where A, B, C are the control factors.

The "■" and "□"points in the graphs can be interpreted as follows:
The "■"points fallen between the upper and lower dash lines are within the control range;
The "■"points fallen outside the upper and lower dash lines are out of the control range;
The "□" points represents non-numeric parameter values (*).

If you see any points fallen outside the control range, do the following steps until the problem is solved. If all the steps have failed, contact Mindray customer service department or your local distributor for assistance.

1. Check the upper left corner of the screen for error messages. Refer to **Chapter 11 Troubleshooting Your Analyzer** for solutions to any displayed error messages;
2. Check the $\overline{X}$ －R settings for inappropriate entries;
3. Do the background check. In case of an abnormal background result, refer to **Chapter 11 Troubleshooting Your Analyzer** for solutions;
4. Re-run the control;
5. Run another vial of control;
6. Check if the analyzer needs to be calibrated.

■ Browsing QC results

Press [↑] or [↓] to review the preceding or following screen; press [←] or [→] to review the preceding or following result. The $\overline{X}$ or R value of the current point (the one the cursor is located at) is displayed below the $\overline{X}$ or R. The location of the current point is displayed in the "**No.**" field. The analysis time is displayed in the "**Time**" field.

■ Printing $\overline{X}$ and R graphs

Press [PRINT] to print out the displayed $\overline{X}$ and R graphs.

■ Exiting the "$\overline{X}$**-R Graph**" screen

Press [MENU] to exit to the system menu, or press [MAIN] to exit to the "**Count**" screen.

"$\bar{X}$-R Table" mode

■ Entering the "$\bar{X}$-**R Table**" mode

Press [MENU] to enter the system menu.

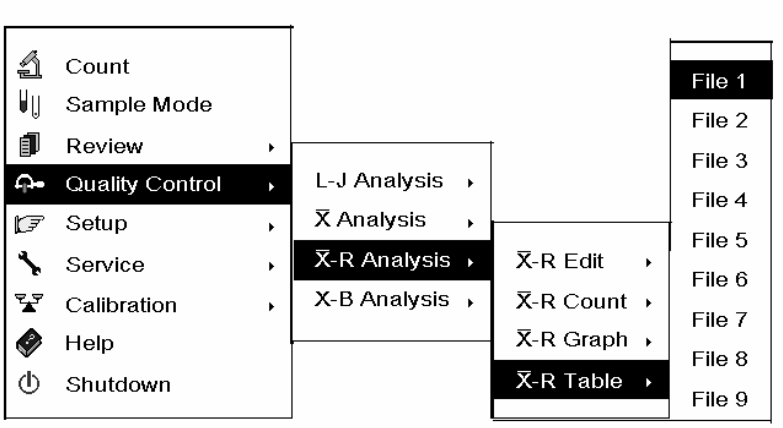


Figure8-43 System menu

SELECT "**Quality Control→ $\bar{X}$-R Analysis →$\bar{X}$-R Table → File 1**" (Figure8-43) shows to enter the "$\bar{X}$-**R Table**" screen (Figure 8-44). Every screen displays 3 results.

X̄-R Table (File 1) | Ready | Whole | 17:36

Lot No.: 76462 Exp. Date: 07-03-2005

NO.			1		2		3	
Date			01-05-00		01-05-00		01-05-00	
Time			03:06		03:03		02:58	
	Total Ave	Total Dev	Mean	Dev	Mean	Dev	Mean	Dev
WBC	10.15	0.122	10.4	0.0	10.0	0.1	10.1	0.1
Lymph#	4.53	0.000	4.6	0.0	4.4	0.0	4.5	0.0
Gran#	4.81	0.113	5.0	0.0	4.8	0.1	4.8	0.1
Lymph%	43.93	0.230	44.0	0.3	43.8	0.1	44.2	0.1
Gran%	47.97	0.438	48.0	0.6	48.0	0.3	47.8	0.2
HGB	129.3	1.01	131	1	130	0	130	0
RBC	4.386	0.1129	4.41	0.07	4.38	0.13	4.39	0.11
HCT	39.80	1.138	40.1	0.6	39.8	1.2	39.9	1.1
MCV	90.95	0.112	90.9	0.1	90.9	0.1	91.0	0.1
MCH	29.51	0.443	29.7	0.3	29.6	0.8	29.5	0.7
MCHC	325.9	5.13	327	3	326	10	324	9
PLT	268.1	8.96	264	10	270	13	272	5

MENU | [PgUp, PgDn]Browse,[DEL]Delete all QC data.

Figure 8-44"$\bar{X}$ -R Table"screen

■ Browsing results of $\bar{X}$-R analyses

Press [PgUp] or [PgDn] to review the preceding or following screen.

- Deleting results of $\bar{X}$-R analyses

Press [DLE] and a message box will pop up to ask you whether to delete all the QC results saved in this file, as Figure 8-45 shows. ***CLICK*** "**Enter**" to confirm the deletion; ***CLICK*** "**Cancel**" to abort the deletion.

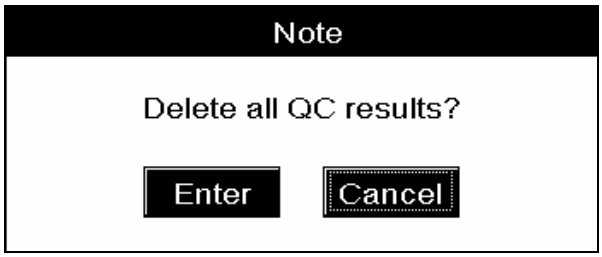


Figure 8-45 A message box to confirm the deletion

- Printing $\bar{X}$-R analysis results

Press [PRINT] to print out all the $\bar{X}$-R analysis results saved in this file by the printer.

- Exiting the "$\bar{X}$**-R Table**" screen

Press [MENU] to exit to the system menu; press [MAIN] to exit to the "**Count**" screen.

8.5 “X-B Analysis” Program

The X-B analysis is a weighted moving average analysis that uses values obtained from patient samples. It was proposed by Brian Bull, M.D. using the 3 red cell indices, MCV, MCH and MCHC to indicate the hematology instrument performance. Effective use of X-B requires randomization of samples and a normal cross section of patients to prevent skewing of indices.

It is recommended the X-B analysis be enabled when the sample volume of your laboratory is greater then 100 samples per day.

8.5.1 Editing X-B Settings

- Entering the “**X-B Edit**” screen

Press [MENU] to enter the system menu.

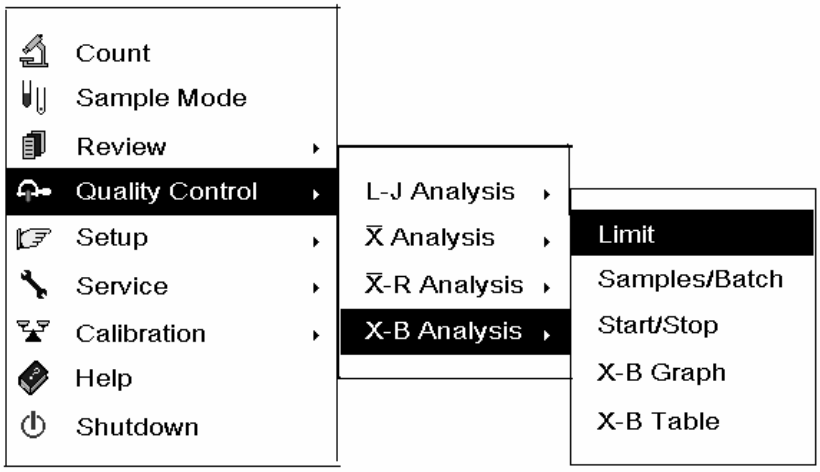


Figure 8-46 System menu

SELECT “**Quality Control → X-B Analysis → Limit**” (Figure 8-46) to enter the “**Limit**” screen (Figure8-47).

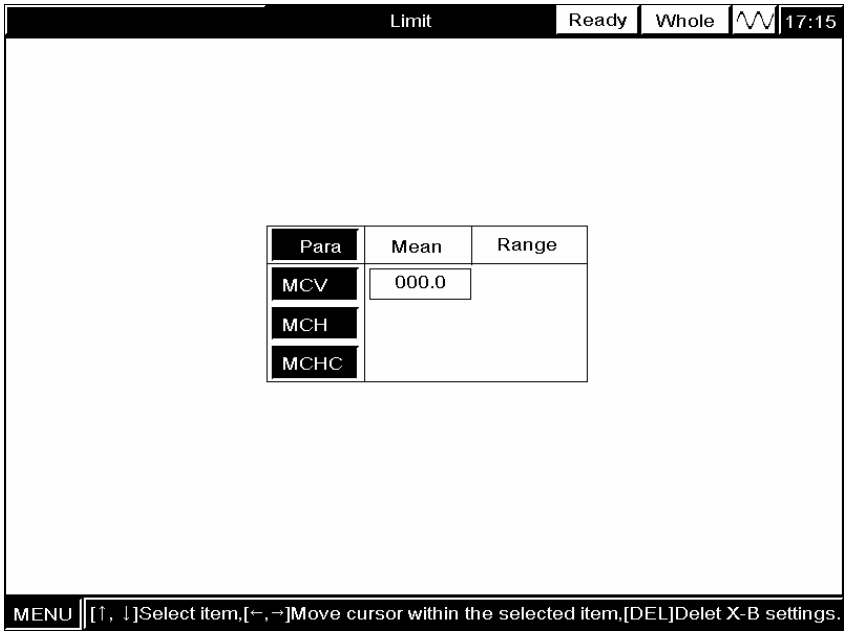


Figure8-47 "Limit" screen

If there are saved QC results and settings, you need to delete them first. Press [DEL] and a message box will pop up to confirm the deletion, as Figure8-48 shows.

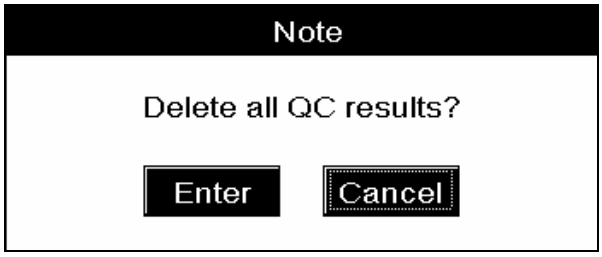


Figure8-48 A message box to confirm the deletion

CLICK "**Enter**" to confirm the deletion; ***CLICK*** "**Cancel**"to abort the deletion.

■ Entering the expected results (mean) and limits (range)

The expected results vary depending on laboratories. It is recommended they are obtained by calculating the averages of at least 500 random patient samples. The recommended limit is 3% - 5%.

NOTE

- **Be sure to calibrate your analyzer before trying to establish the expected results by calculating the averages of random patient samples.**

ENTER the expected results (mean) and limits (range) respectively into the "**Mean**" box and "**Range**" boxes of the parameters to be included in the QC run.

- Deleting settings

Press [DEL] to delete all the settings.

- Printing settings

Press [Print] to print out all the settings.

- Exiting the "**Limit**" screen

Press [MENU] (or [MAIN] if you want to go directly to the "**Count**" screen) to exit the "**Limit**" screen.

A message box shown in Figure8-49 will pop up, if :
There is a paremter for which you have entered only the expected result or the limit;
or
There is a parameter whose expected result is less than or equal to the limit.

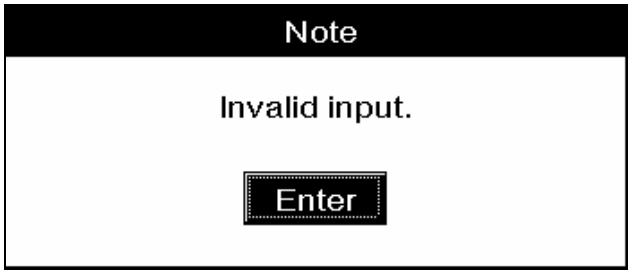


Figure8-49 An "Invalid input" message box

CLICK "**Enter**" to save the changes and exit to the system menu (or the "**Count**" screen);
CLICK "**Cancel**" to abort the changes and exit to the system menu (or the "**Count**" screen).

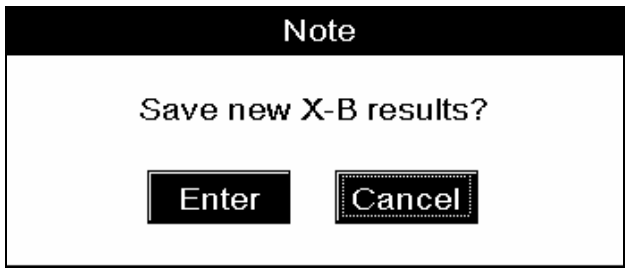


Figure8-50 A message box to save the changes

8.5.2 Setting frequency of the X-B analysis

The X-B analysis is performed on batches of certain number of patient samples. To determine how many samples are to be included in every batch, follow the steps below to do so.

- Entering the "**Samples/Batch**"screen

Press [MENU] to enter the system menu.

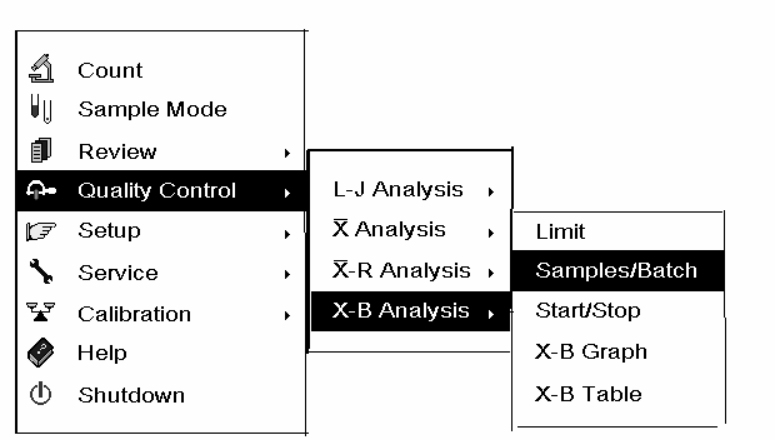


Figure8-51 System menu

SELECT "**Quality Control→ X-B Analysis → Samples/Batch**" (Figure8-51) to enter the "Samples/Batch" screen (Figure8-52).

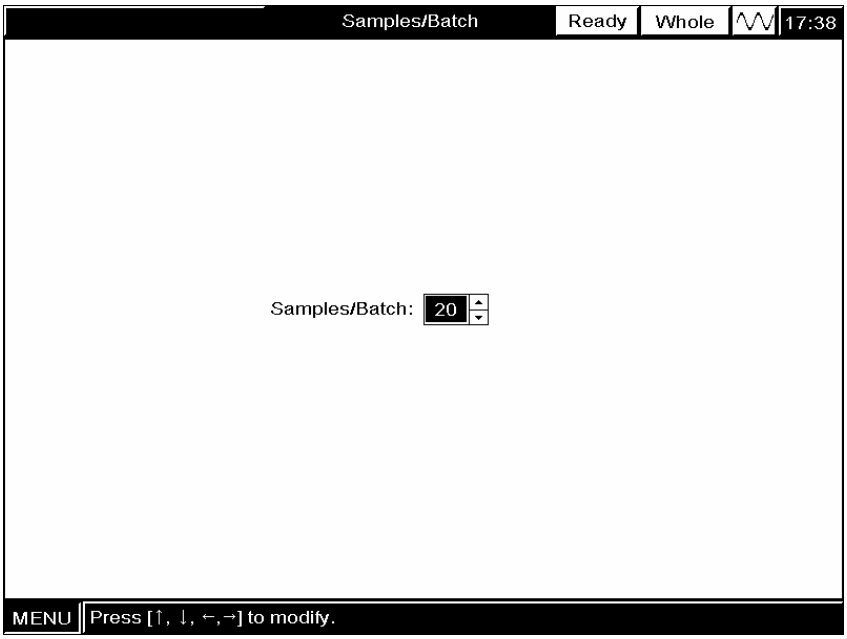


Figure8-52 "Samples/Batch"screen

- Setting Samples/Batch

ENTER the desired number, which should be 20 to 200. 20 is recommended.

- Exiting the "**Sample/Batch**" screen

Press [MENU] to exit to the system menu; press [MAIN] to exit to the "**Count**" screen.

8.5.3 Enabling/Disabling X-B Analysis

- Entering the "**Start/Stop**"screen

Press [MENU] to enter the system menu.

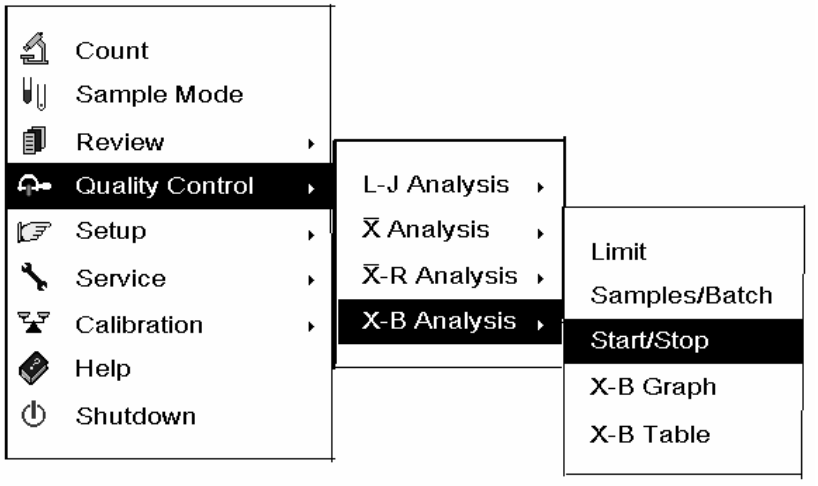


Figure8-53 System menu

SELECT "**Quality Control→ X-B Analysis→ Start/Stop**" (Figure8-53) to enter the "**Start/Stop**" screen (Figure8-54).

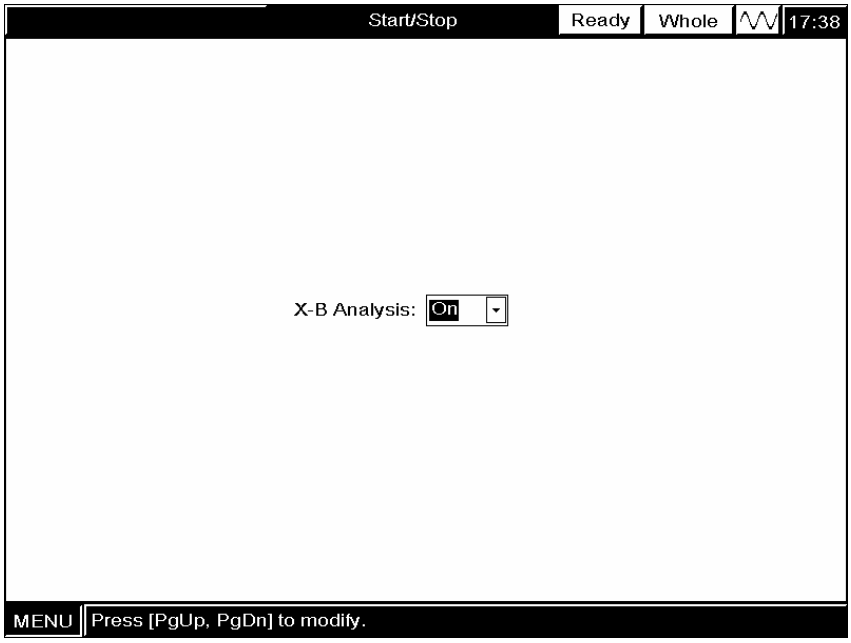


Figure8-54 Enabling/disabling X-B analysis

Random samples are required for the X-B analysis. In case of known samples of a particular type (oncology, neonatal and so forth) that will seriously interfere with the X-B results, disable the X-B analysis.

- Enabling/disabling X-B analysis

Press [PgUp] or [PgDn] to activate/deactivate X-B analysis.

- Exiting the "**Limit**" screen

Press [MENU] (or [MAIN] if you want to go directly to the "**Count**" screen) to exit the "**Limit**" screen and a message box will pop up to remind you to save the changes, as Figure8-55 shows. ***CLICK*** "**Enter**" to save the changes and exit to the system menu (or the "**Count**" screen); ***CLICK*** "**Cancel**" to abort the changes and exit to the system menu (or the "**Count**" screen).

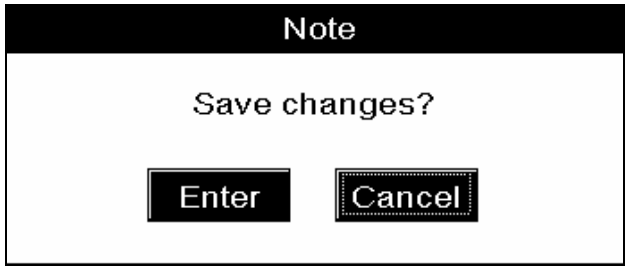


Figure8-55 A message box to confirm the changes

8.5.4 Performing X-B Analysis

Once enabled, the X-B analysis will be performed on batches of patient samples of the defined number (20 - 200). The analysis results will be displayed on the X-B graph as well as the X-B table.

8.5.5 Reviewing X-B Analysis Results

You can review the X-B analysis results in either the "**X-B Graph**" mode or "**X-B Table**" mode.

"X-B Graph" mode

- Entering the "**X-B Graph**" screen

Press [MENU] to enter the system menu.

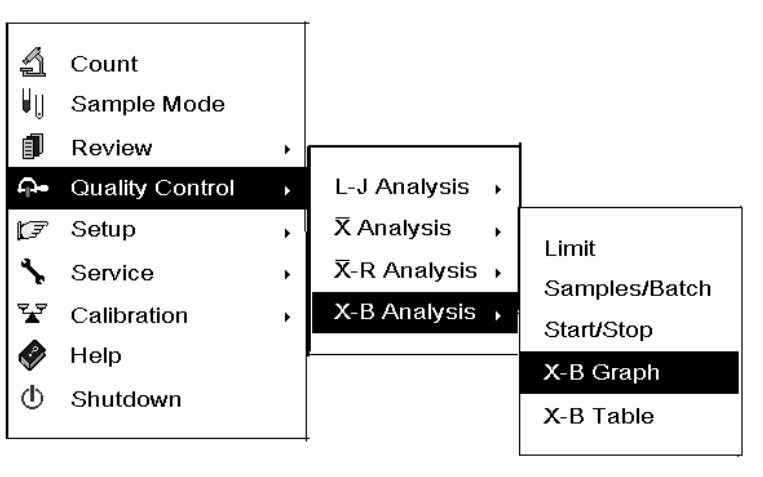


Figure8-56 System menu

SELECT "**Quality Control → X-B Analysis → X-B Graph**" (Figure8-56) to enter the "**X-B Graph**" screen (Figure8-57).

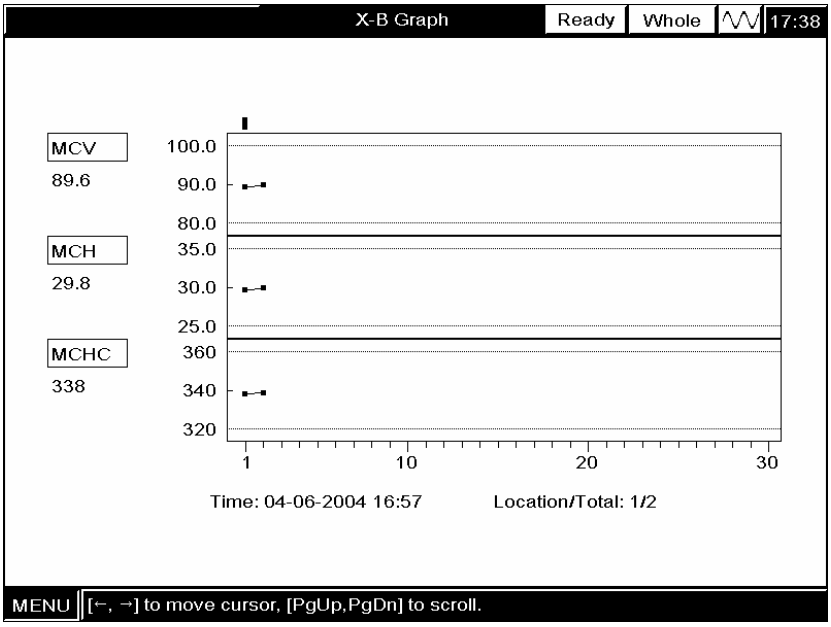


Figure8-57 "X-B Graph" screen

The saved X-B analysis results are sequentially displayed in the X-B graph, the latest on the utmost left (No.1).

The X-B graph can be interpreted as follows:

■ The x-coordinate represents the number of X-B analyses performed; the y-coordinate represents the results of the X-B analyses;

■ For every parameter, its X-B graph can display maximum 500 points, 30 points per screen;

■ For every parameter, the upper dash line represents the expected result + limit;

■ For every parameter, the upper dash line represents the expected result – limit;

■ For every parameter (e.g. MCV), the three numbers to the left of the X-BFigure are defined as follows:

100 – expected result ＋ limit;
90 – expected result;
80 – expected result – limit.

The "■"points fallen between the upper and lower dash lines are within the expected ranges;
The "■"points fallen outside the upper and lower dash lines are out of the expected ranges

If you see any points fallen outside the control range, do the following steps until the problem is solved. If all the steps have failed, contact Mindray customer service department or your local distributor for assistance.

1. Check the upper left corner of the screen for error messages. Refer to **Chapter 11 Troubleshooting Your Analyzer** for solutions to any displayed error messages;

2. Check the X-B settings for inappropriate entries;
3. Do the background check. In case of an abnormal background result, refer to **Chapter 11 Troubleshooting Your Analyzer** for solutions;
4. Run the controls;
5. Check if the analyzer needs to be calibrated.

■ Browsing X-B analysis results

Press [↑] or [↓] to review the preceding or following screen; press[←] or [→] to review the preceding or following result. The parameter value of the current point (the one the cursor is located at) is displayed below the parameter. The location of the current point is displayed in the "**No.**" field. The analysis time is displayed in the "**Time**" field.

■ Printing X-B graphs

Press [PRINT] to print out the displayed X-B graphs.

■ Exiting the "**X-B Graph**" screen

Press [MENU] to exit to the system menu, or press [MAIN] to exit to the "**Count**" screen.

"X-B Table" mode

■ Entering the "**X-B Table**"mode

Press [MENU] to enter the system menu.

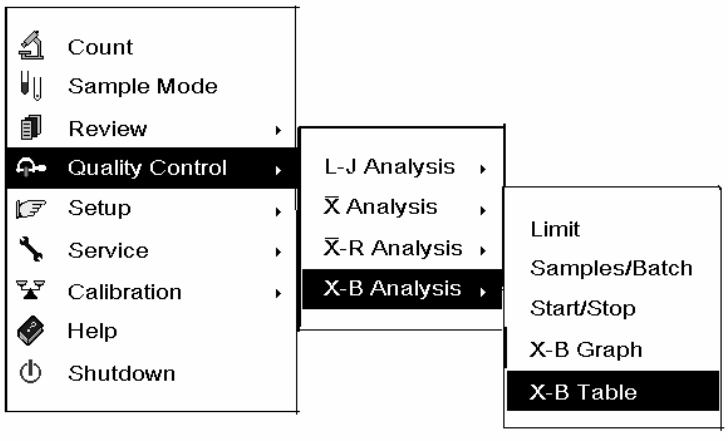


Figure8-58 System menu

SELECT "**Quality Control → X-B Analysis → X-B Table → File 1**" (Figure8-58) to enter the "**X-B Table**" screen (Figure8-59). Every screen displays 5 results. The parameter value fallen outside the expected range will be flagged "H" (higher than the upper limit) or "L" (lower than the lower limit).

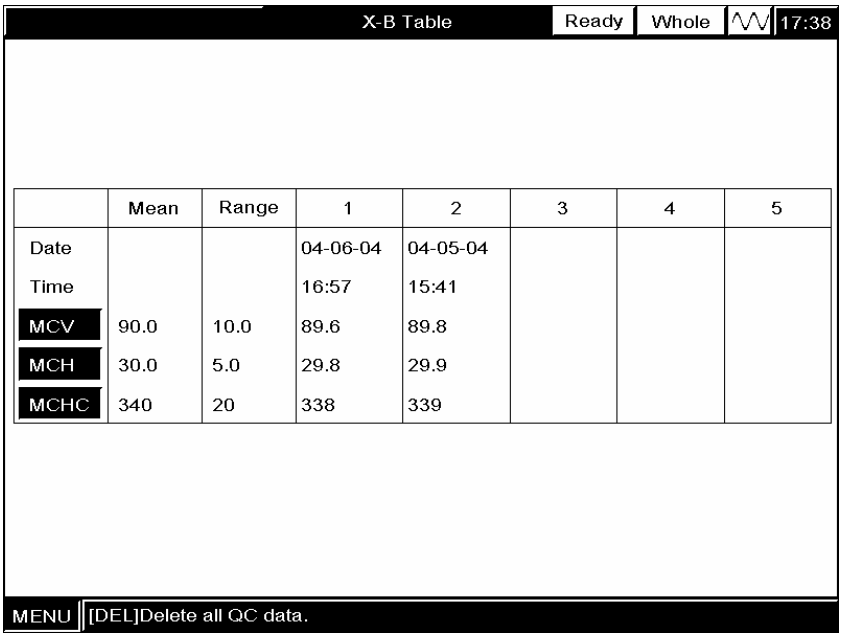


Figure8-59 "X-B Table"screen

- Browsing X-B analysis results

Press [PgUp] or [PgDn] to review the preceding or following screen.

- Deleting X-B analysis results

Press [DLE] and a message box will pop up to ask you whether to delete all the X-B analaysis results saved in this file, as Figure8-60 shows. ***CLICK*** "**Enter**" to confirm the deletion; ***CLICK*** "**Cancel**" to abort the deletion.

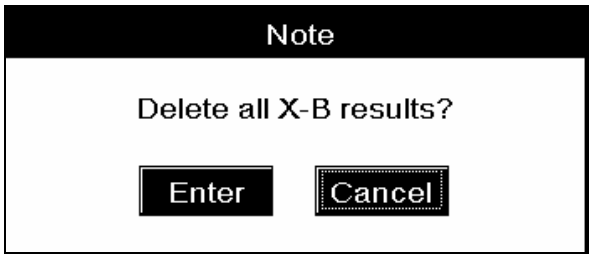


Figure8-60 A message box to confirm the deletion

- Printing X-B analysis results

Press [PRINT] to print out the displayed results by the printer.

- Exiting the "**X-B Table**" screen

Press [MENU] to exit to the system menu; press [MAIN] to exit to the "**Count**" screen.

9 Using the Calibration Programs

9.1 Introduction

Purpose of the calibration is to maintain system accuracy. Quality of the calibration depends on the calibration materials and reagents used. You should only use the calibrators and reagents specified by Mindray for the calibration. Be sure to store and use the calibrators and reagents as instructed by their instructions for use.

9.2 When to calibrate

You should run the calibration program if

- It is the first time the analyzer has been used;
- Certain major component (s) of the analyzer has been changed;
- The quality control results indicate there may be a problem.

NOTE

- **All of the measured parameters must be calibrated before readings of this analyzer can be used as valid analysis results.**

9.3 How to Calibrate

The analyzer provides 3 calibration programs: manual calibration, auto calibration using commercial calibrators and auto calibration using fresh blood samples. Two sets of calibration factors are prepared respectively for the whole blood mode and the predilute mode.

9.3.1 Preparing Your Analyzer

Do the following pre-calibration procedures before calibration. If problems are detected during these checks, do not attempt to calibrate the analyzer. If necessary, call Mindray customer service department or your local distributor for assistance.

Check and make sure enough reagents have been prepared for the calibration. You need to start over the calibration if the reagents run out during the process.

Do the background check. If the analyzer alarms for abnormal background results, see **Chapter 11 Troubleshooting Your Analyzer** for solutions.

Enter the "**Count**" screen and run a vial of normal control 11 consecutive times. Enter the "**Review**" screen to check the reproducibility of the second to eleventh runs and make sure they meet the following requirements.

Table 9-1 Reproducibility

Parameter	Expected range	CV%
WBC	7.0 - 15.0 $\times 10^9$ / L	≤ 2.0
RBC	3.50 - 6.00 $\times 10^{12}$ / L	≤ 1.5
HGB	110 - 180 g/L	≤ 1.5
MCV	80.0 - 110.0 fL	≤ 0.5
PLT	150 - 500 $\times 10^9$ / L	≤ 4.0

At the "**Count**" screen, run a vial of high control three consective times and then immediately run the diluent three consective times, calculate the carryover per the following equation.

$$\text{Carryover}(\%) = \frac{\text{First low - level sample result} - \text{Third low - level sample result}}{\text{Third high - level sample result} - \text{Third low - level sample result}} \times 100\%$$

The calculated carryovers shall meet the following requirements: WBC, RBC and HGB shall be no greater than 0.5 % ; PLT shall be no greater than 1%.

It is recommended that you create a log table for your analyzer. This log table should contain all necessary information that is pertinent to your analyzer. Suggested items that you may want to include in the log table are:

- Calibration date
- Supplier of calibrator
- Lot number
- Expected results and limits
- Result of background check.

Enter the administrator password instructed in **Chapter 5.4.1** and then choose one or several parameters among WBC, RBC, HGB, MCV and PLT for calibration.

9.3.2 "Auto Calibration" Program

Press [MENU] to enter the system menu.

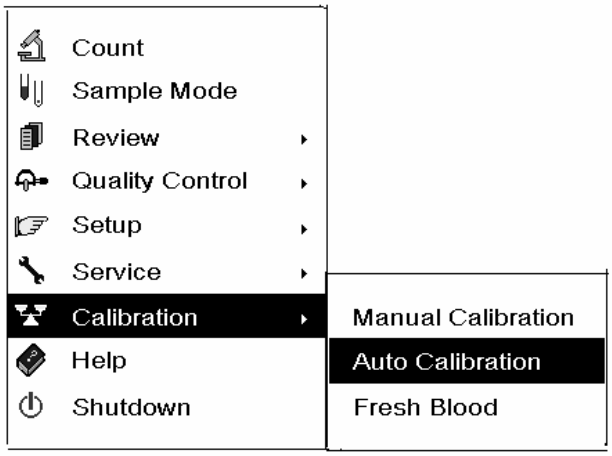


Figure9-1 System menu

SELECT "**Calibration→ Auto Calibration**" (Figure9-1) to enter the "**Auto Calibration**" screen (Figure9-2).

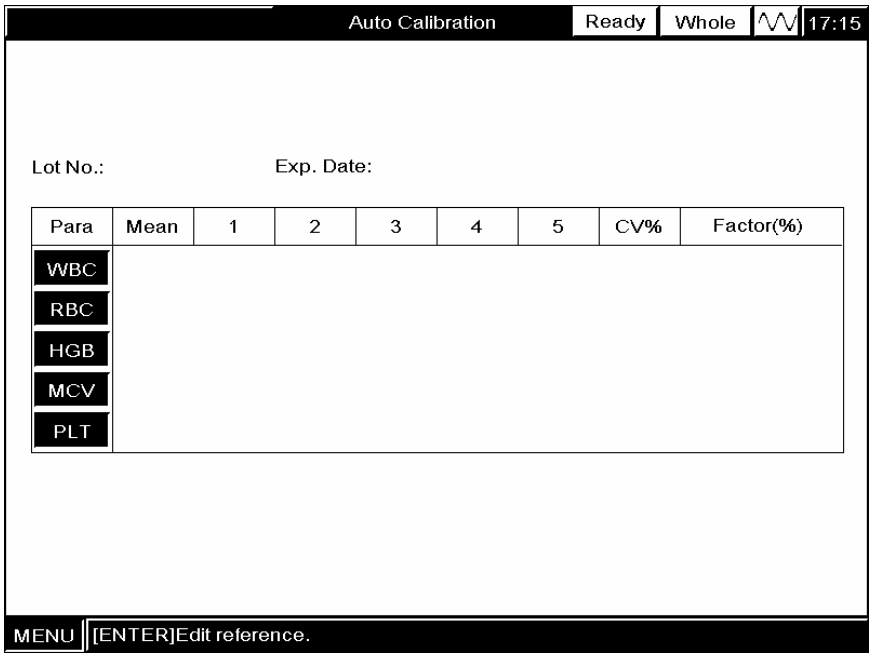


Figure9-2 "Auto Calibration" screen

Selecting the count mode

Press [MENU] and ***SELECT*** "**Mode**" to enter the "**Mode**" screen.
SELECT "**Whole Blood**" or "**Predilute**" from ***the "*Sample Mode*" pull-down list*.**
Press [MENU] and ***SELECT*** "**Count**" to enter the "**Count**" screen.

NOTE

- **When switching from the predilute mode to the whole blood mode, the analyzer will automatically wash the fluidic system.**

Editing calibration settings

Press [ENTER] to activate the edit boxes.

- Entering lot number

ENTER the lot number of the calibrator to be used into the "**Lot No.**" box.

- Entering Exp. Date

ENTER the expiration date of the calibrator to be used into the "**Exp. Date**" box.

- Entering the expected results (mean) and limits (range)

ENTER the expected results (mean) and limits (range) respectively into the "**Mean**" and "**Range**" boxes of the parameters to be included in the calibration.

NOTE

- **Refer to the instructions of use of the calibrators for information on the lot number, expiration date, expected results and limits.**
- **When editing the settings, if you want to correct an erroneous entry, *MODIFY* the wrong digit.**

When you have finished editing the interested settings, press [ENTER] to deactivate the edit boxes.

Running the calibrator

NOTE

- **Be sure to use the Mindray- specified calibrator. Using calibrator other than the specified will lead to misleading results.**
- **Refer to the instructions of use of the controls for how to store and use the calibrator.**
- **Be sure to use fused silica glass/plastic test tubes and 20μL borosilicate glass capillary tubes.**
- **Be sure to keep the sample probe tip away from the tube bottom, otherwise the aspiration volume may be inaccurate.**
- **When the aspiration is done, remove the sample tube only when the sample probe is out of the tube.**

- **Samples, controls, calibrators and waste are potentially infectious. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them in the laboratory.**

⚠ WARNING

- **The sample probe tip is sharp and may contain biohazardous materials. Exercise caution to avoid contact with the probe when working around it.**
- **Do not re-use such disposable products.**

In the whole blood mode:

1. Be sure the **System Status** area displays "**Ready**" and **Count Mode** area displays "**Whole**";
2. Present a vial of mixed calibrator to the sample probe so that the tip is well into the tube, and press the aspirate key. The **System Status** area will display "**Running**" and the analyzer will start aspirating sample;
3. When you hear the beep and the sample probe is out of the vial, remove the calibrator. The sample probe will retract into the analyzer and the analysis progress will be displayed on the screen;
4. When the analysis is finished, the result will be displayed on the screen and the sample probe will be replaced.

In the predilute mode:

1. Be sure the **System Status** area displays "**Ready**" and **Count Mode** area displays "**Predilute**";
2. Press [DILUENT] and a message box will pop up to instruct you how to dispense the diluent into the sample tube, as Figure 9-3 shows;

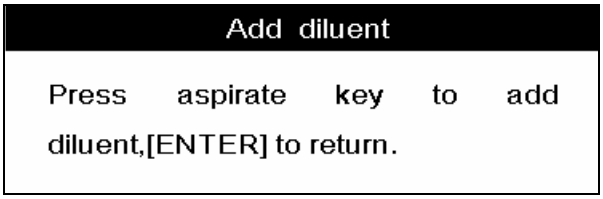


Figure 9-3 An "Add diluent" message box

3. Present a clean sample tube to the sample probe and make sure the tube is tilted towards the probe, as Figure 9-4 shows, to avoid spills and bubbles. Press the aspirate key to dispense 0.7ml of diluent (the dispensing volume is controlled by the analyzer) into the tube;

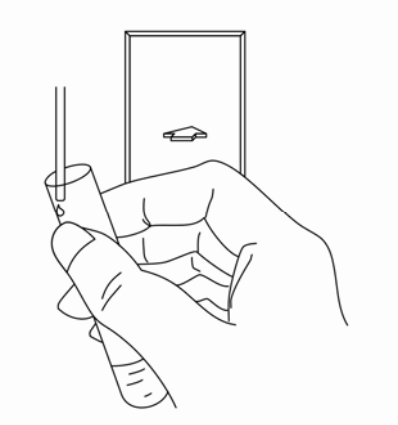


Figure 9-4 How to dispense diluent

4. When the dispensing is finished, press [ENTER] to close the box;
5. Add 20μL of calibrator to the diluent and shake the tube to mix the sample.

NOTE

- **Be sure to keep dust from the prepared diluent.**
- **After mixing the calibrator with the diluent, be sure to wait 3 minutes before running it.**
- **Be sure to run the prediluted calibrators within 30 minutes after the mixing.**
- **Mix any pre-diluted calibrator that has been prepared for a while before running it.**
- **Be sure to evaluate predilute stability based on your laboratory's sample population and sample collection techniques or methods.**

6. Present the mixed calibrator to the sample probe so that the tip is well into the tube, and press the aspirate key. The **System Status** area will display "**Running**" and the analyzer will start aspirating sample;
7. When you hear the beep and the sample probe is out of the tube, remove the calibrator. The sample probe will retract into the analyzer and the analysis progress will be displayed on the screen;
8. When the analysis is finished, the result will be displayed on the screen and the sample probe will be replaced.

NOTE

- **If the analyzer detects WBC/RBC clogging or bubbles during the analysis, the corresponding error messages will be displayed in the upper left corner of the screen and the results of all the related parameters will be invalidated. See Chapter 11 Troubleshooting Your Analyzer for solutions.**
- **If the ambient temperature is outside the specified operating range, the analyzer will alarm you for abnormal ambient temperature and the analysis results may be unreliable. See Chapter 11 Troubleshooting Your Analyzer for solutions.**

Saving the calibration results

If non-numerci parameter values ("***") are obtained, a message box will pop up to warn you, as Figure 9-5 shows.

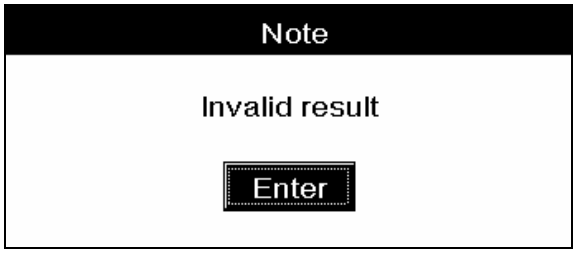


Figure 9-5 A message box to warn you about the invalid results

CLICK "**Enter**" to clear the results.

If all the parameter values obtained are numeric, a message box will pop up to confirm the validity of the results, as Figure 9-6 shows.

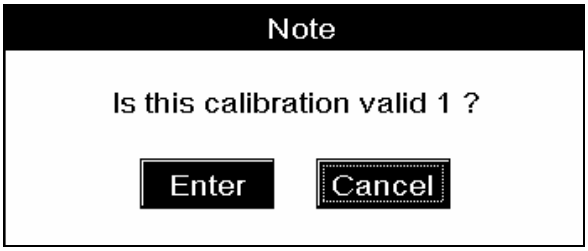
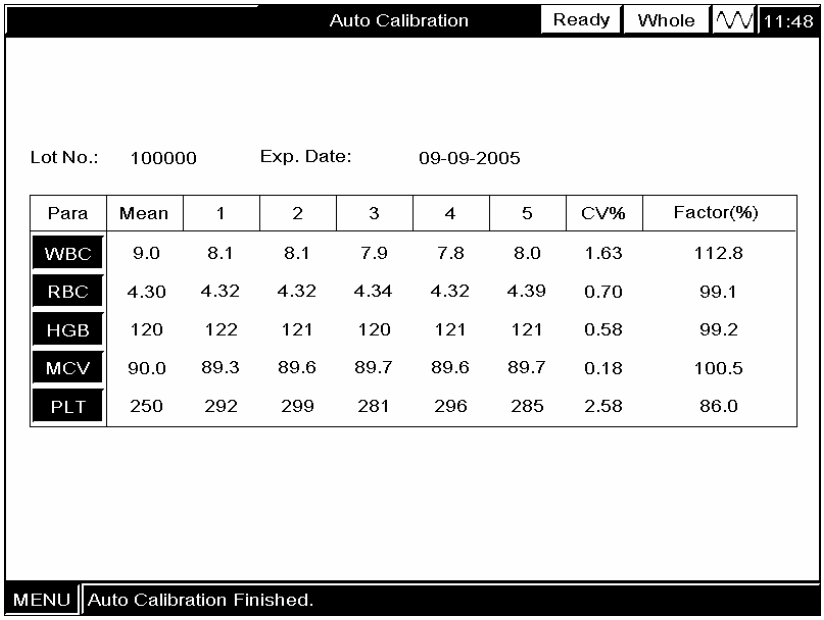


Figure 9-6 A message box to confirm the validity

CLICK "**Enter**" to save the results; ***CLICK*** "**Cancel**" to abort the result. The saved results will be displayed on the screen.

Repeat the above steps to run the calibrator 3 – 5 times (5 is recommended) and the analyzer will automatically calculate the CVs and calibration factors, as Figure 9-7 shows. Be sure the CVs meet the requirements of Table 9-1.



Para	Mean	1	2	3	4	5	CV%	Factor(%)
WBC	9.0	8.1	8.1	7.9	7.8	8.0	1.63	112.8
RBC	4.30	4.32	4.32	4.34	4.32	4.39	0.70	99.1
HGB	120	122	121	120	121	121	0.58	99.2
MCV	90.0	89.3	89.6	89.7	89.6	89.7	0.18	100.5
PLT	250	292	299	281	296	285	2.58	86.0

Figure 9-7 Results of the auto calibration

The calculated calibration factor should be within the 75％ - 125％. Any calculated value that falls between 0％-75％ or 125％-9999％ will be flagged with a "*". Other values will not be displayed. In case of an empty calibration factor, try to find out the reason and if necessary, contact Mindray customer service department or your local distributor for assistance.

Verifying new calibration factors

Press [MAIN] to enter the "**Count**" screen, a message box will pop up to confirm the new calibration factors, as Figure 9-8 shows.

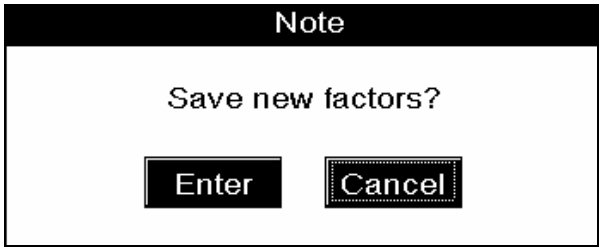


Figure 9-8 A message box to confirm the new calibration factors

CLICK "**Enter**" to save the new calibration factors to the "**Manual Calibration**" screen and enter the "**Count**" screen.

At the "**Count**" screen, run the calibrator or a normal control material at least 5 consecutive times and calculate the mean of the results. The means should be within the expected ranges supplied by the manufacturer. If not, contact Mindray customer service department or your local distributor for assistance.

Printing new calibration factors

Press [PRINT] to print out the new calibration factors.

Exiting the "Auto Calibration" screen

Press [MENU] to exit to the system menu or [MAIN] to exit to the "**Count**" screen. A message box will pop up to confirm the new calibration factors, as Figure 9-8 shows. ***CLICK*** "**Enter**" to save the new factors to the "**Manual Calibration**" screen and exit to the system menu or the "**Count**" screen; ***CLICK*** "**Cancel**" to abort the new factors and exit to the system menu or the "**Count**" screen.

9.3.3 “Fresh Blood” Program

Press [MENU] to enter the system menu.

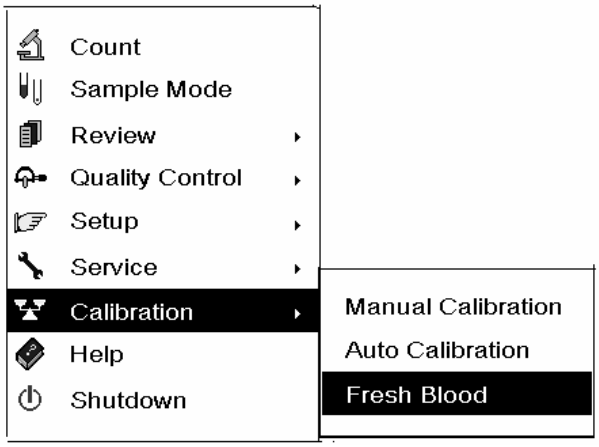


Figure 9-9 System menu

SELECT “**Calibration** →“**Fresh Blood**” (Figure 9-9) to enter the “**Fresh Blood**” screen (Figure9-10).

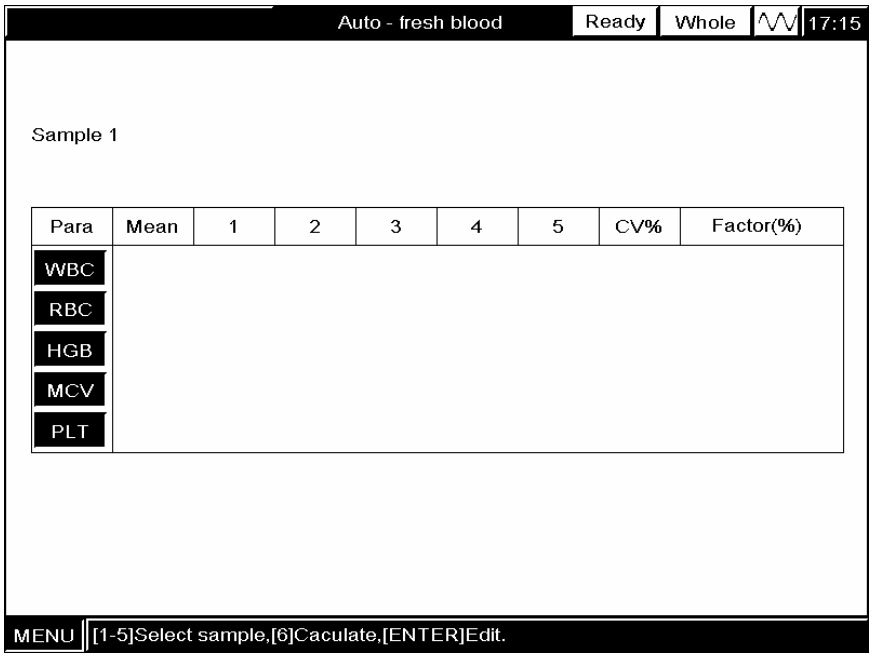


Figure9-10 “Fresh Blood” screen

Complete the fresh blood calibration as instructed below:

Selecting count mode

Press [MENU] and ***SELECT*** “**Mode**” to enter the “**Mode**” screen. ***SELECT*** “**Whole Blood**” **or** “**Predilute**”***from the “Sample Mode” pull-down list***.

NOTE

- **Once switching from the predilute mode to the whole blood mode, the analyzer will automatically wash the fluidic system.**

Editing calibration settings

1. Press [1]...[5] to switch among "**Sample 1**" to "**Sample 5**" to select the sample for calibration. The following introduction takes Sample 1 as the example.
2. Press [ENTER] to enter the editing state of the expected value of sample 1.
3. ENTER the expected result into the "Mean" edit box. To correct any errorneous entry, ***MODIFY*** the digit. After you have finished the editing, press [ENTER] to exit the editing state.

Running the sample

After you have finished editing the calibration settings of Sample 1, refer to the sample handling and analysis procedures introduced in **Chapter 6 Operating Your Analyzer** and prepare the fresh blood samples in the selected count mode to perform the fresh blood calibration.

NOTE

- **You should prepare 3 – 5 normal fresh blood samples for the calibration.**

Saving calibration results

If non-numeric parameter values ("***") are obtained, a message box will pop up to warn you, as Figure9-11 shows.

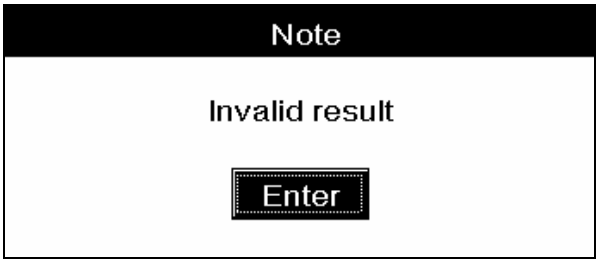


Figure9-11 A message box to warn you about the invalid results

CLICK "**Enter**" to clear the results.

If all the parameter values obtained are numeric, a message box will pop up to confirm the validity of the results, as Figure9-12 shows.

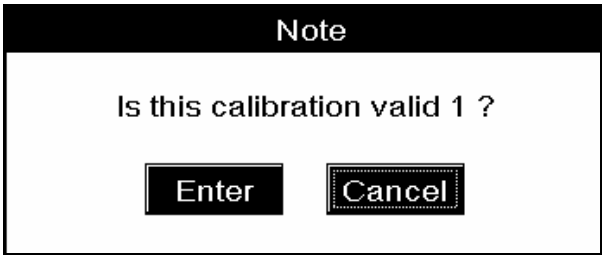


Figure9-12 A message box to confirm the validity

CLICK "**Enter**" to save the results to the "**Auto – fresh blood**" screen; ***CLICK*** "**Cancel**" to abort the result.

NOTE

- **If you press [MENU] to enter the system menu before the average is obtained at the "Calculate" screen, the next time you enter the "Auto-fresh blood" screen a message box will pop up to ask you whether to clear the data of the last calibration; If you press [MAIN] to exit to the "Count"screen before the average is obtained at the "Calculate" screen, the next time you enter the "Auto-fresh blood" screen a message box will pop up to ask you whether to clear the data of the last calibration**

Repeat the above steps to run the sample 3 – 5 times (5 is recommended) and the analyzer will automatically calculate the CV and calibration factor, as Figure9-13 shows. Be sure the CVs meet the requirements of Table 9-1.

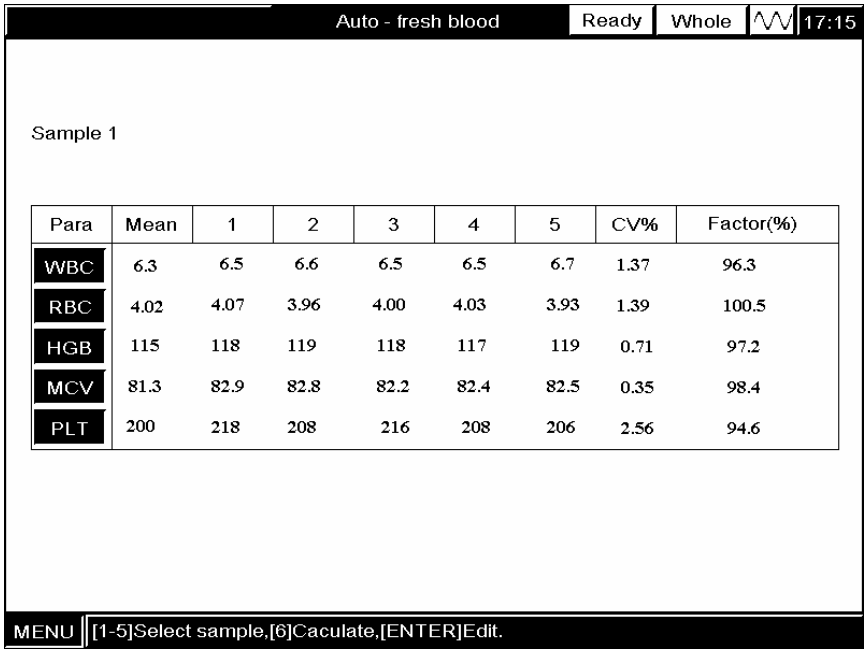
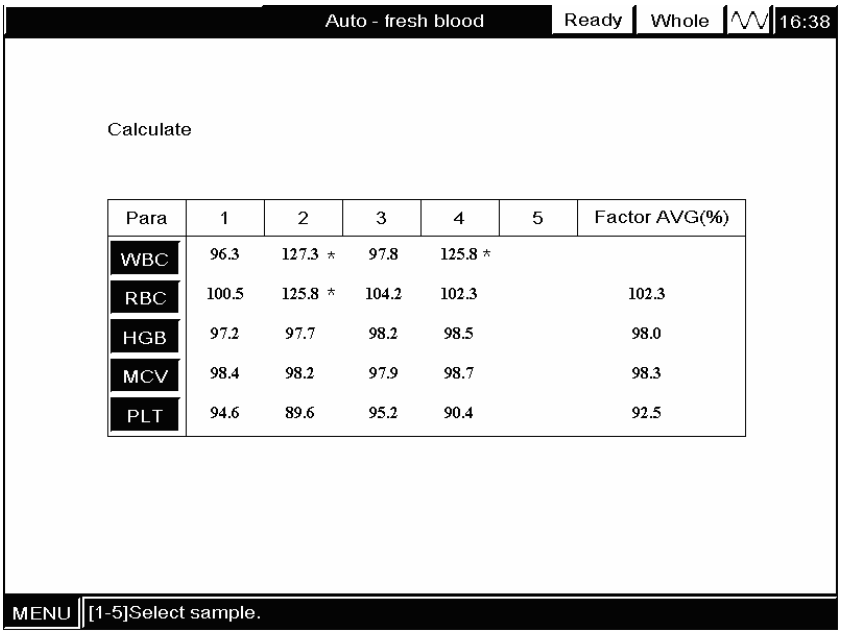


Figure9-13 "Fresh Blood" screen

The calculated calibration factors should be within the 75％ - 125％. Any calculated value that falls between 0％-75％ or 125％-9999％ will be flagged with a "*". Other values will not be displayed. In case of an empty calibration factor, try to find out the reason and if necessary, contact Mindray customer service department or your local distributor.

You can enter the "**Auto – fresh blood**" screen of "**Sample 2**"... "**Sample 5**" by pressing [2] ... [5]. Follow the calibration steps of sample 1 to run at least another two fresh blood samples. When you have obtained the calibration factors of at least 3 fresh blood samples, you can press [6] to enter the "Calculate" screen as Figure9-14 shows. At the screen, the digits "**1**", "**2**", "**3**", "**4**"and "**5**"respectively correspond to the calibration factors of samples 1 - 5.

The "**Calculate**" screen can maximum display 5 sets of calibration factors. The calculated calibration factors should be within the 75％ - 125％. Any calculated factor that falls between 0％ - 75％ or 125％ - 9999％ will be flagged with a "*". Other values will not be displayed. In case of an empty calibration factor, try to find out the reason and if necessary, contact Mindray customer service department or your local distributor. For every parameter, the analyzer will calculate the average calibration factor, which serves as the new calibration factor, only when there are at least 3 valid calibration factors（e.g. RBC in Figure9-14）. Otherwise, the average calibration factor will be empty (e.g. WBC in Figure9-14).



Para	1	2	3	4	5	Factor AVG(%)
WBC	96.3	127.3 *	97.8	125.8 *		
RBC	100.5	125.8 *	104.2	102.3		102.3
HGB	97.2	97.7	98.2	98.5		98.0
MCV	98.4	98.2	97.9	98.7		98.3
PLT	94.6	89.6	95.2	90.4		92.5

Figure9-14 "Calculate" screen

Verifying new calibration factors

Press [MAIN] to enter the "**Count**" screen, a message box will pop up to confirm the new calibration factors, as Figure 9-15 shows.

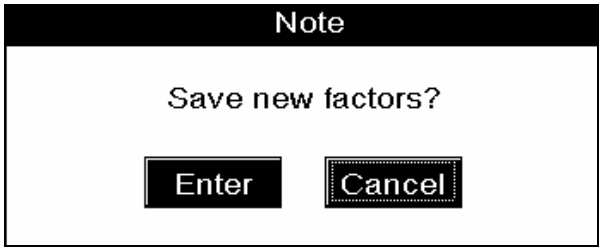


Figure 9-15 A message box to confirm the new calibration factors

CLICK "**Enter**" to save the new calibration factors to the "**Manual Calibration**" screen and enter the "**Count**" screen.

Test the new calibration factors either of the following ways.

- Method one:

Prepare 3-5 normal fresh blood samples and run each one of them on a reference analyzer at least 3 consecutive times. Calculate the mean (MEAN 1) and SD (SD 1) of every sample.

Run the same samples on your analyzer for the same number of times and calculate the mean (MEAN 2). The MEAN 2 should be within MEAN 1 ± 2SD. If any of the sample fails to reach the criterion, call Mindray customers service department or your local distributor.

- Method two:

At the "**Count**" screen, run the calibrator at least 5 consecutive times and calculate the means of the results. The means should be within the expected ranges supplied by the manufacturer. If not, contact Mindray customer service department or your local distributor.

Printing new calibration factors

Press [PRINT] to print out the new calibration factors.

Exiting the "Fresh Blood" screen

Press [MENU] to exit to the system menu. A message box will pop up to confirm the new calibration factors, as Figure 9-15 shows. ***CLICK*** "**Enter**" to save the new factors to the "**Manual Calibration**" screen and exit to the system menu; ***CLICK*** "**Cancel**" to abort the new factors and exit to the system menu.

9.3.4 Manual Calibration Program

If needed, you may run the calibration material at the "**Count**" screen and calculate the calibration factors manually.

Press [MENU] to enter the system menu. ***SELECT*** "**Count**" (Figure7-1) to enter the "**Count**" screen (Figure9-17).

Complete the manual calibration steps as introduced below.

Selecting count mode

Press [MENU] and ***SELECT*** "**Mode**" to enter the "**Mode**" screen. ***SELECT*** "**Whole Blood**" **or** "**Predilute**"***from the "*****Sample Mode*****" pull-down list***.

NOTE

- **Once switching from the predilute mode to the whole blood mode, the analyzer will automatically wash the fluidic system.**

Figure9-16 System menu

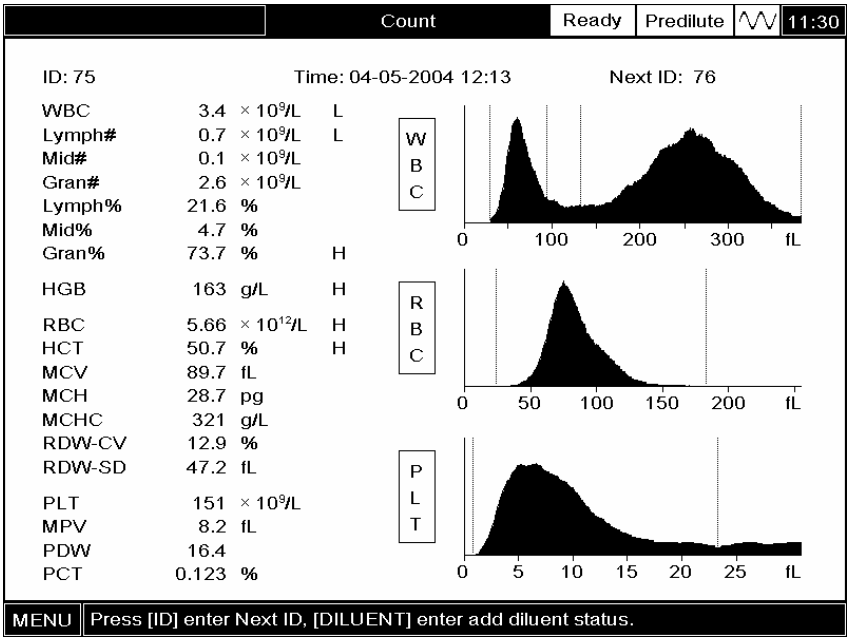


Figure9-17 "Count" screen

Running the calibration material

After you have selected the desired sample mode, refer to the sample handling and analysis procedures introduced in **Chapter 6 Operating Your Analyzer** and run the calibration material with known expected results 11 consecutive times.

Checking the reproducibility

When you have finished running the calibration material, enter the "**Sample Table Review**" screen to check the Mean, SD and CV% of the 2nd to 11th runs. Press [MENU] to enter the system menu as Figure9-18 shows.

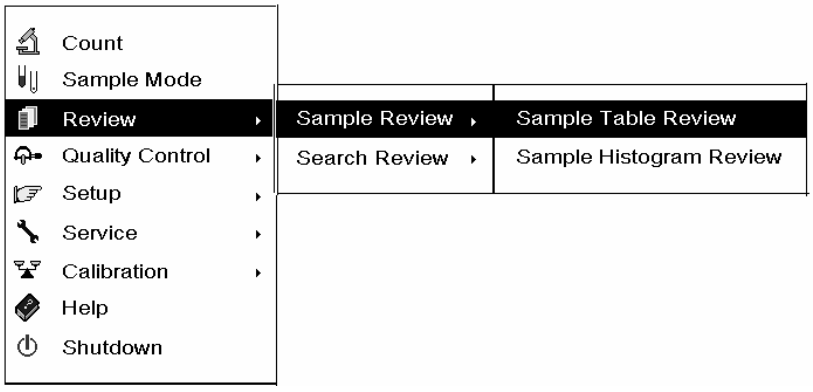
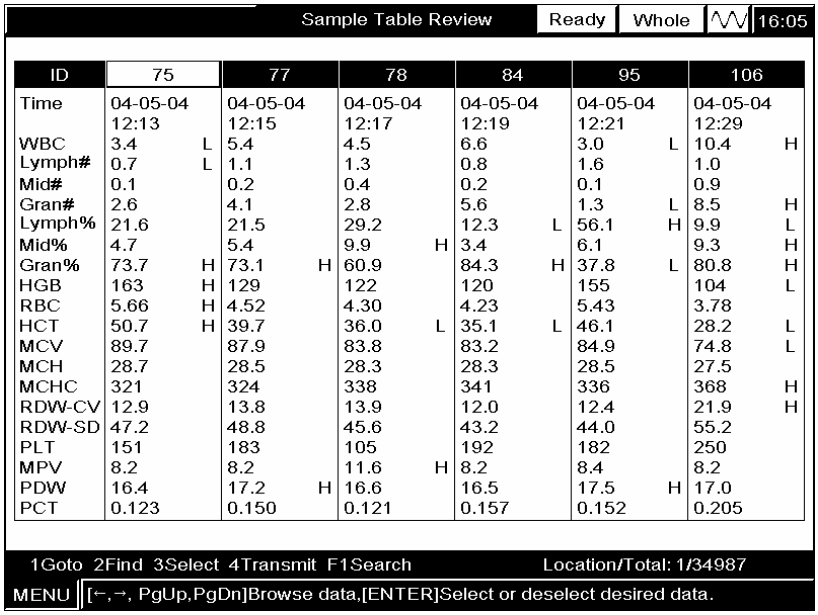


Figure9-18 System menu

SELECT "**Review → Sample Review → Sample Table Review**" to enter the "**Sample Table Review**" screen, as Figure 9-19 shows.



ID	75		77		78		84		95		106	
Time	04-05-04 12:13		04-05-04 12:15		04-05-04 12:17		04-05-04 12:19		04-05-04 12:21		04-05-04 12:29	
WBC	3.4	L	5.4		4.5		6.6		3.0	L	10.4	H
Lymph#	0.7	L	1.1		1.3		0.8		1.6		1.0	
Mid#	0.1		0.2		0.4		0.2		0.1		0.9	
Gran#	2.6		4.1		2.8		5.6		1.3	L	8.5	H
Lymph%	21.6		21.5		29.2		12.3	L	56.1	H	9.9	L
Mid%	4.7		5.4		9.9	H	3.4		6.1		9.3	H
Gran%	73.7	H	73.1	H	60.9		84.3	H	37.8	L	80.8	H
HGB	163	H	129		122		120		155		104	L
RBC	5.66	H	4.52		4.30		4.23		5.43		3.78	
HCT	50.7	H	39.7		36.0	L	35.1	L	46.1		28.2	L
MCV	89.7		87.9		83.8		83.2		84.9		74.8	L
MCH	28.7		28.5		28.3		28.3		28.5		27.5	
MCHC	321		324		338		341		336		368	H
RDW-CV	12.9		13.8		13.9		12.0		12.4		21.9	H
RDW-SD	47.2		48.8		45.6		43.2		44.0		55.2	
PLT	151		183		105		192		182		250	
MPV	8.2		8.2		11.6	H	8.2		8.4		8.2	
PDW	16.4		17.2	H	16.6		16.5		17.5	H	17.0	
PCT	0.123		0.150		0.121		0.157		0.152		0.205	

Figure9-19 "Sample Table Review"screen

Check the reproducibility as instructed in **Chapter 7.11**. If the reproducibility meets the requirements listed in Table 9-1, record the Mean of the 10 runs. If the means of any parameter falls outside the expected range (see the instructions for use of the calibrator), calibrate the analyzer as instructed below, otherwise the calibration is not necessary.

If the reproducibility of the calibrated parameter does not meet the requirements of Table 9-1, you must try to find out the reason and re-run the calibrator after you have solved the problem. If necessary, contact Mindray customer service department or your local distributor for assistance.

It is recommended that you create a log table for your analyzer. This log table should contain all necessary information that is pertinent to your analyzer. Suggested items that you may want to include in the log table are:

- Calibration date
- Supplier of calibrator
- Lot number
- Expected results and limits
- Result of background check.

Enter the administrator password instructed in **Chapter 5.4.1** and then choose one or several parameters among WBC, RBC, HGB, MCV and PLT for calibration.

Calculating the new calibration factors manually

Use the following formula to calculate the new calibration factor.

$$\text{new factor} = \frac{\text{old factor} \times \text{expected result}}{\text{recorded mean}}$$

The calculated new calibration factor should be within 75%-125%. If not, try to find out the reason and if necessary, call Mindray customer service department or your distributor for assistance.

Entering the manually calculated factors

Press [MENU] to enter the system menu.

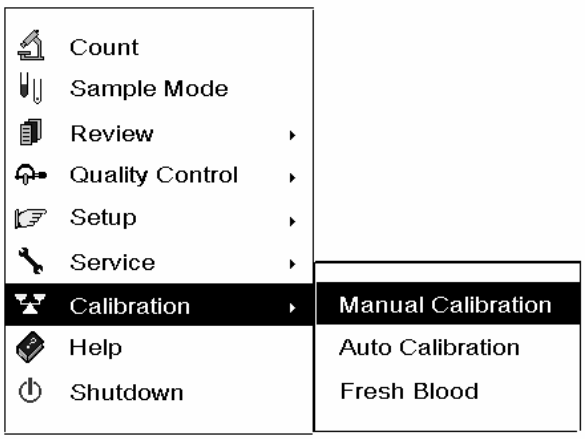


Figure 9-20 System menu

SELECT "**Calibration → Manual**" (Figure 9-20) to enter the "**Manual Calibration**" screen (Figure 9-21).

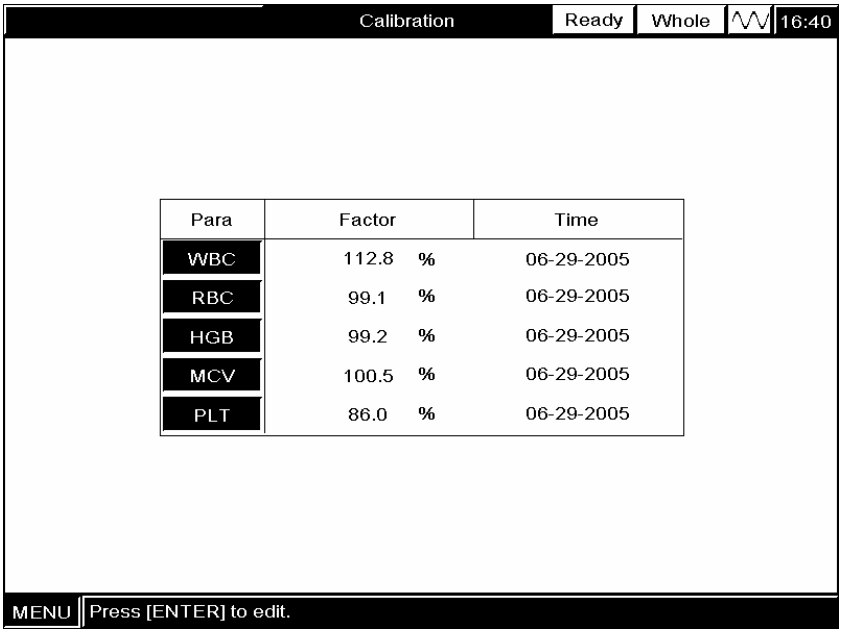


Figure 9-21 "Manual Calibration" screen

Press [ENTER] to activate the edit boxes as Figure 9-22 shows.

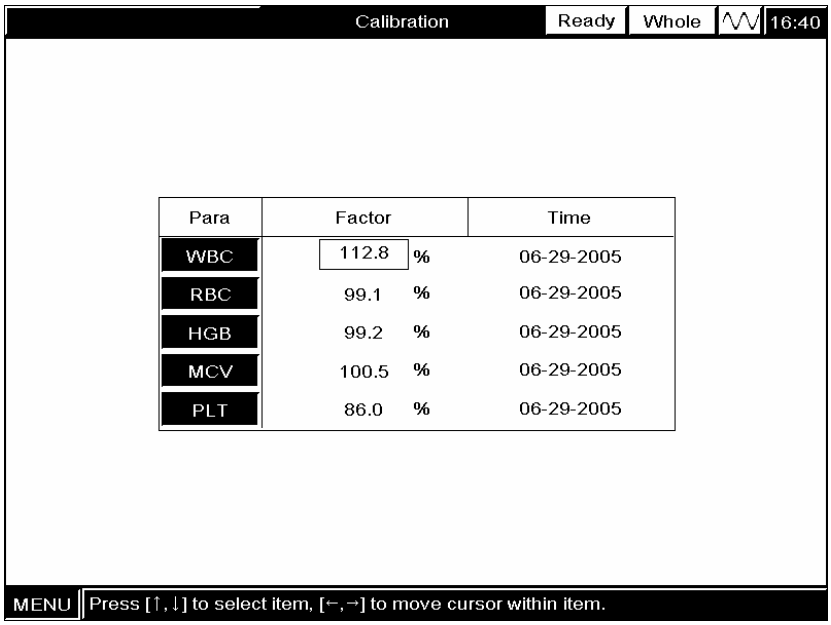


Figure 9-22 Edit boxes activated

ENTER the calculated calibration factor into the corresponding boxes. To correct an erroneous entry, ***DELETE*** the wrong digit and enter the correct digit.

Verifying new calibration factors

Press [MAIN] to enter the "**Count**" screen, a message box will pop up to confirm the new calibration factors, as Figure 9-23 shows.

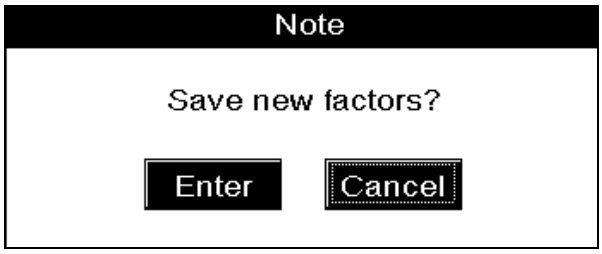


Figure 9-23 A message box to confirm the new calibration factors

CLICK "**Enter**" to save the new calibration factors to the "**Manual Calibration**" screen and enter the "**Count**" screen.

If you have used the calibrator for the manual calibration, verify the new calibration as instructed in **Chapter 9.2.2**; If you have used a fresh blood sample for the manual calibration, verify the new calibration as instructed in **Chapter 9.2.3**.

Printing new calibration factors

Press [PRINT] to print out the current calibration factors.

Exiting the “Manual Calibration” screen

Press [MENU] to exit to the system menu. A message box will pop up to confirm the new calibration factors, as Figure 9-23 shows. ***CLICK*** “**Enter**” to save the new factors to the “**Manual Calibration**” screen and exit to the system menu; ***CLICK*** “**Cancel**” to abort the new factors and exit to the system menu.

10 Maintaining Your Analyzer

10.1 Introduction

Routine preventive maintenance and cleaning are required to keep the BC-3000 Plus in good operating condition. Cleanliness is important in keeping your analyzer operating efficiently and accurately. The analyzer has automatic cleaning functions that are performed during normal operation. These built-in functions keep the fluidic system clean.

In spite of the automatic cleaning functions, Mindray encourages you to routinely perform the required maintenance to lengthen the operational life of your analyzer and to minimize system problems that lead to imprecision and inaccuracy. This chapter describes the recommended preventive maintenance procedures and provides instructions for preparing the analyzer for an extended period of inactivity.

⚠ CAUTION

- **Do not perform any maintenance procedures that are not described in this chapter. Performing unauthorized maintenance procedures can damage your analyzer.**
- **In case of problems not specified in this manual, contact Mindray customer service department or your local distributor for assistance.**
- **Only Mindray-supplied parts can be used for maintenance. For any questions, contact Mindray customer service department or your local distributor.**

10.2 General Guidelines

Maintenance Period	Content of Maintenance
Everyday	If you are to use this analyzer 24 hours a day, be sure to perform the "**E-Z cleanser cleaning**" procedure everyday.
	Run the QC program everyday. See **Chapter 7 Using Quality Control Programs** for details.
Every three days	If you are to use this analyzer 24 hours a day, be sure to perform the "**Probe cleanser cleaning**" procedure every three days.
Every Week	If you shut down your analyzer every day and follow the specified shutdown procedure to do that, you need to perform the "**Probe cleanser cleaning**" procedure every week**.**
Every Month	You should use the supplied probe localizer to calibrate the position of the probe to that of the probe wipe. The analysis result is sensitive to their alignment.
As needed	When you think the baths might be contaminated, perform the "**Clean the baths**" procedure.
	When the analyzed whole blood samples add up to 300 or prediluted samples add up to 150, the analyzer will remind you to perform the "**Probe cleanser cleaning**" procedure.
	When the analyzed whole blood samples add up to 2,000 or prediluted samples add up to 4,000, the analyzer will remind you to perform the "**Clean wipe block**" procedure.
	When this analyzer is not to be used for two weeks, be sure to perform the "**Prepare to ship**" procedure to empty and wash the fluidic lines and then wipe the analyzer dry and wrap it up for storage.
	To obtain reliable analysis results, this analyzer needs to work in a normal status. Be sure to run the "**System Test**" items regularly to check the status of this analyzer.
	When this analyzer gives alarms for clogging, you can perform the "**Flush Apertures**" or "**Zap Apertures**" procedure, or press [FLUSH] to unclog the apertures.

	If you see other error messages, see **Chapter 11 Troubleshooting**, for solutions.

10.3 Using the "Maintenance" Program

Press [MENU] to enter the system menu. ***SELECT*** "**Service → Maintenance**" (Figure10-1) to enter the "**Maintenance**" screen (Figure10-2).

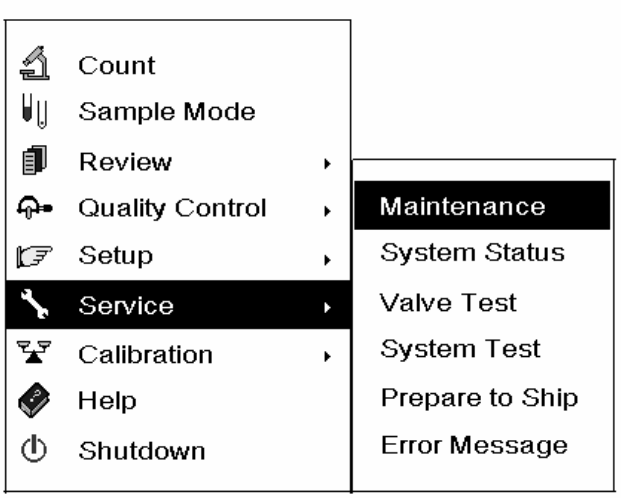


Figure10-1 System menu

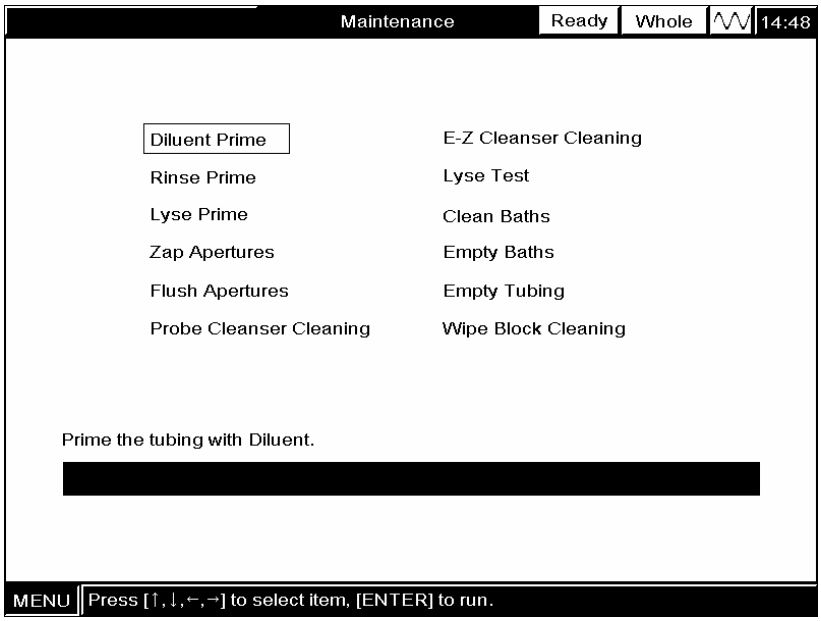


Figure10-2 "Maintenance" screen

Totally 12 maintenance procedures are available at the "**Maintenance**" screen.

- Diluent Prime
- Rinse Prime
- Lyse Prime
- Zap Apertures
- Flush Apertures
- Probe Cleanser Cleaning
- E-Z Cleanser Cleaning
- Lyse Test
- Clean Baths
- Empty Baths
- Empty Tubing
- Wipe Block Cleaning

10.3.1 Diluent Prime

- **Samples, controls, calibrators and waste are potentially infectious. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them in the laboratory.**

NOTE

- **Be sure to keep the reagents still for a while before using them.**
- **After installing a new container of diluent, rinse or lyse, do a background check to ensure the background results are normal.**

You should perform the "**Diluent Prime**" procedure to prime the diluent tubing with diluent when

- there are bubbles in the tubing; or
- the diluent in the tubing is contaminated; or
- the old diluent ran out and a new container of diluent is installed.

At the "**Maintenance**" screen, ***SELECT*** "**Diluent Prime"** to prime the tubing with diluent and the priming progress will be displayed at the bottom of the screen, Figure10-3 shows. When the priming is done, the screen displays "**Diluent Prime End**".

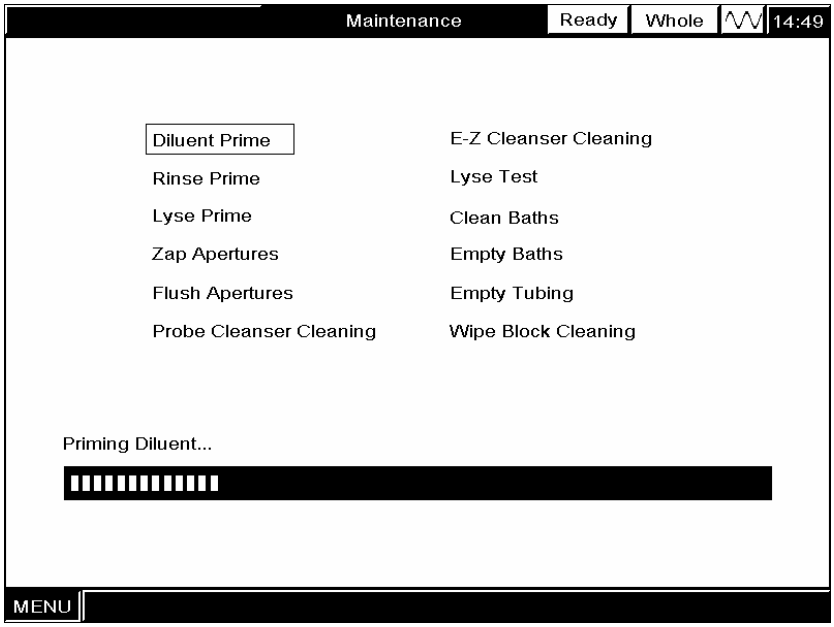


Figure10-3 "Diluent Prime" screen

10.3.2 Rinse Prime

- **Samples, controls, calibrators and waste are potentially infectious. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them in the laboratory.**

NOTE

- **Be sure to keep the reagents still for a while before using them.**
- **After installing a new container of diluent, rinse or lyse, do a background check to ensure the background results are normal.**

You should perform the "**Rinse Prime**" procedure to prime the rinse tubing with rinse when

- there are bubbles in the tubing; or
- the rinse in the tubing is contaminated; or
- the old rinse ran out and a new container of rinse is installed.

At the "**Maintenance**" screen, ***SELECT*** "**Rinse Prime**" to prime the tubing with rinse and the priming progress will be displayed at the bottom of the screen, as Figure10-4 shows. When the priming is done, the screen displays "**Rinse Prime End**".

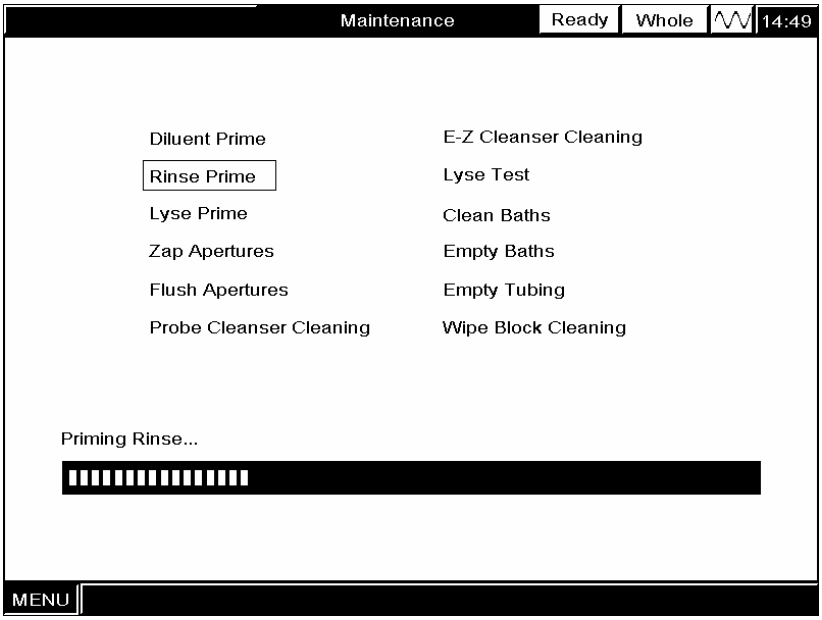


Figure10-4 Rinse Priming screen

10.3.3 Lyse Prime

- **Samples, controls, calibrators and waste are potentially infectious. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them in the laboratory.**

NOTE

- **Be sure to keep the reagents still for a while before using them.**
- **After installing a new container of diluent, rinse or lyse, do a background check to ensure the background results are normal.**

You should perform the "**Lyse Prime**" procedure to prime the lyse tubing with lyse when

- there are bubbles in the tubing; or
- the lyse in the tubing is contaminated; or
- the old lyse ran out and a new container of lyse is installed.

At the "**Maintenance**" screen, ***SELECT*** "**Lyse Prime**" to prime the tubing with lyse and the priming progress will be displayed at the bottom of the screen, as Figure10-5 shows. When the priming is done, the screen will display "**Lyse Prime End**".

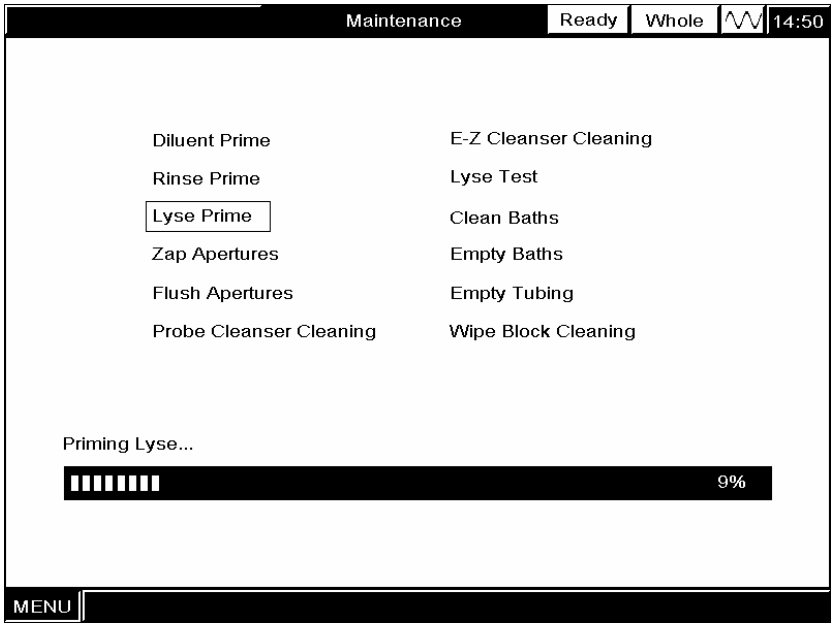


Figure10-5 Lyse priming

10.3.4 Zap Apertures

You can perform the "**Zap Aperture**" procedure to unclog the apertures or prevent clogging.

At the "**Maintenance**" screen, ***SELECT*** "**Zap Aperture**" to zap the apertures and the zapping progress will be displayed at the bottom of the screen, as Figure10-6 shows. When the zapping is done, the screen will display "**Zap Apertures End**".

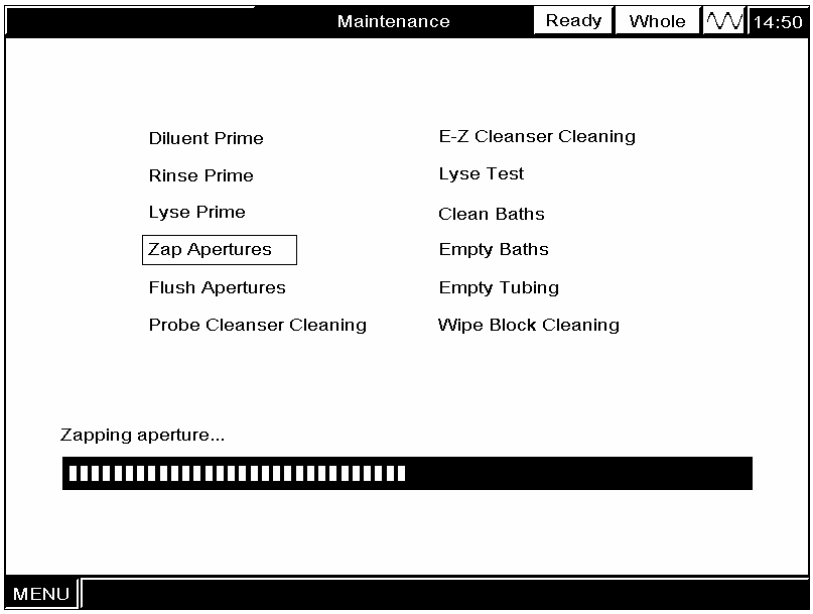


Figure10-6 Zapping aperture

10.3.5 Flush Aperture

You can perform the "**Flush Aperture**" procedure to flush the apertures to unclog the apertures or prevent clogging.

At the "**Maintenance**" screen, ***SELECT*** "**Flush Aperture**" to flush the aperture and the flushing progress will be displayed at the bottom of the screen, as Figure10-7 shows. When the flushing is done, the screen will display "**Flush Apertures End**".

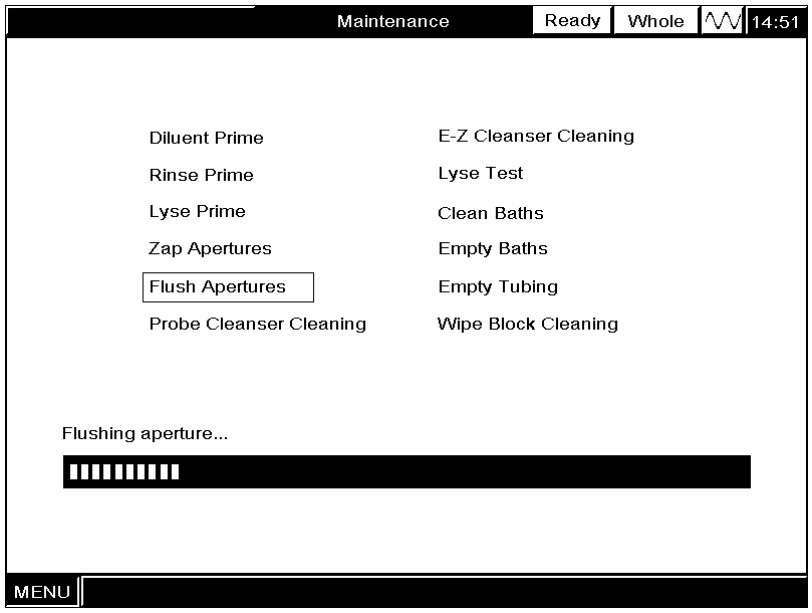


Figure10-7 Flushing apertures

10.3.6 Probe Cleanser Cleaning

- **Samples, controls, calibrators and waste are potentially infectious. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them in the laboratory.**

NOTE

- **The probe cleanser is corrosive. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them in the laboratory.**

You can soak the baths and fluidic lines with the probe cleanser, an alkaline detergent, by performing the "**Probe cleanser cleaning**" procedure. If your analyzer is to run 24 hours a day, you should perform this procedure every 3 days. If you follow the shutdown procedure to turn off your analyzer everyday, you should perform this procedure every week.

Follow the steps given below to do so:

1. At the "**Maintenance**" screen, ***SELECT*** "**Probe Cleanser Cleaning**".
2. Present the cleanser to the probe and press [ENTER] to aspirate the cleanser. When you hear the beep and the sample probe is out of the bottle, remove the cleanser.

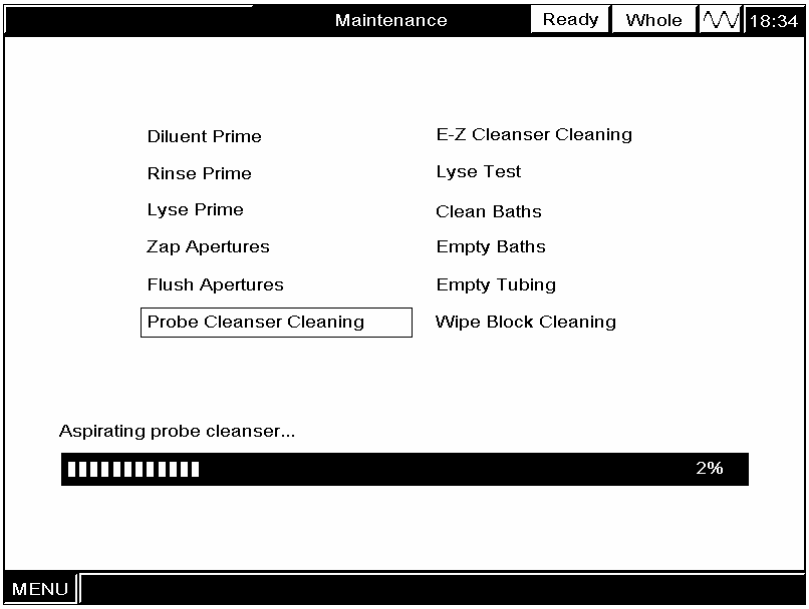


Figure10-8 Priming baths and fluidic lines

3. When the screen reminds you for the second aspiration, present the cleanser to the probe again and press [ENTER]. When you hear the beep and the sample probe is out of the bottle, remove the cleanser and the priming progress is displayed on the screen, as Figure10-9 shows.

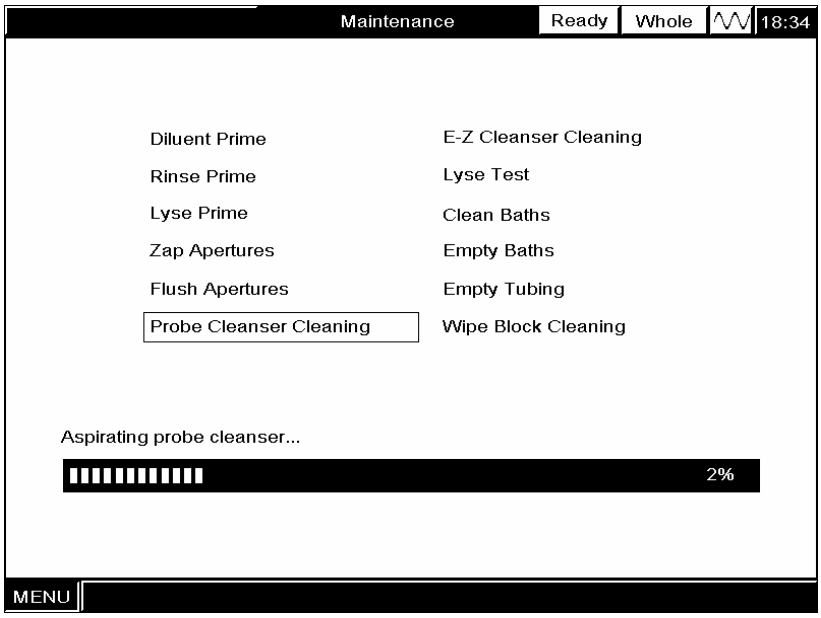


Figure10-9 Priming baths and fluidic lines again

4. The cleaning process will last about 15 minutes and you may press [ENTER] to stop it any time. Note that a shortened priming process may not be as effective as a complete one.

5. When the cleaning is done, press [ENTER] to flush the bath and tubing, after which screen will display "**Probe Cleanser Cleaning End**".

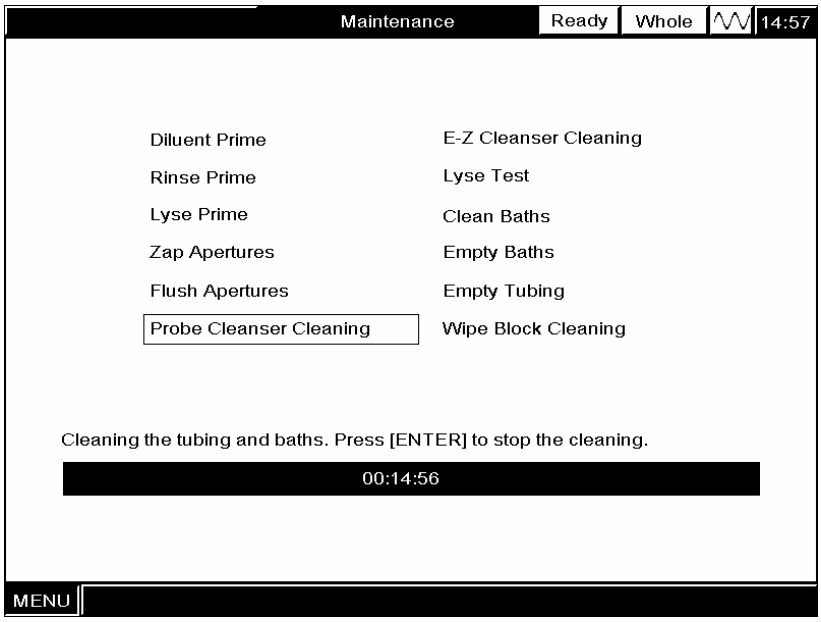


Figure10-10 Cleaning process

To make sure this analyzer functions normally, every time the accumulated analyzed whole blood samples reach 300 or prediluted blood samples reach 150, a message box will pop up to remind you to perform the "**Probe cleanser cleaning**" procedure, as Figure10-11 shows. ***CLICK*** "**Enter**" to proceed with the cleaning; ***CLICK*** "**Cancel**" to cancel the cleaning.

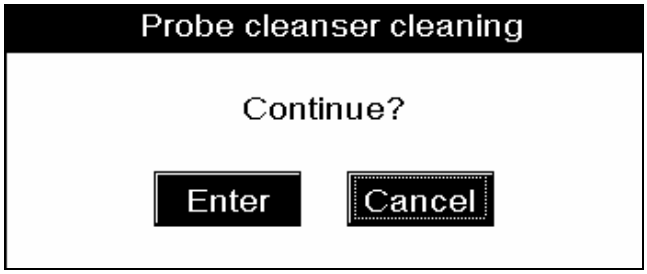


Figure10-11 A message box to confirm the cleaning

10.3.7 E-Z Cleanser Cleaning

- **Samples, controls, calibrators and waste are potentially infectious. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them in the laboratory.**

You can use the E-Z cleanser, an enzyme based, isotonic cleaning solution and wetting agent, to clean the tubing and bath by performing the "**E-Z Cleanser Cleaning**" procedure.
Follow the steps given below to perform the procedure:

1. At the "**Maintenance**" screen, ***SELECT*** "**E-Z Cleanser Cleaning**";
2. Present the cleanser to the probe and press [ENTER] to aspirate the cleanser. When you hear the beep and the sample probe is out of the bottle, remove the cleanser. This analyzer will automatically prime the baths and fluidic lines with the aspirated cleanser and the progress is displayed on the screen, as Figure10-12 shows;

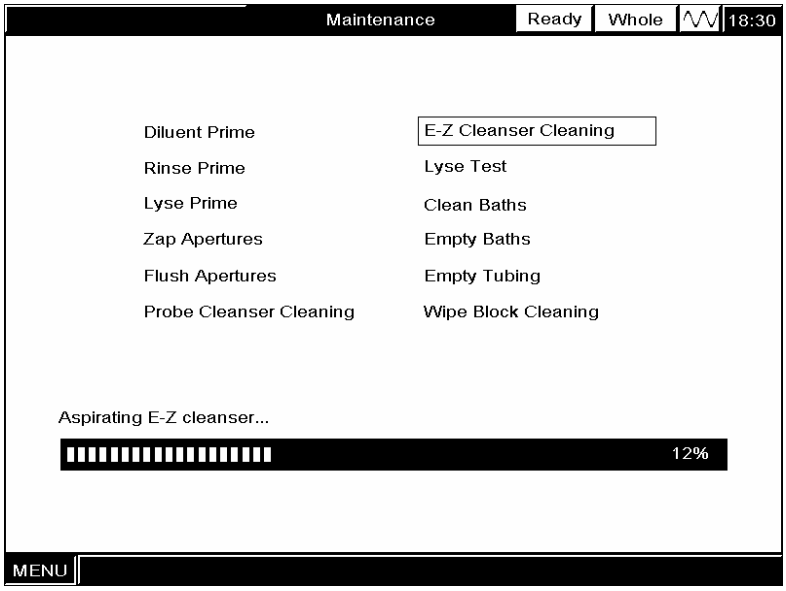


Figure10-12 Priming the baths and fluidic lines

3. When the priming is done, the cleaning process begins, as Figure10-13 shows. The default cleansing time is 8 hours and you may press [ENTER] to stop the process any time;
4. When the cleaning is done, press [ENTER] to drain the baths and fluidic lines, as Figure10-14 shows. When the draining is done, the screen will display "**E-Z Cleanser Cleaning End**".

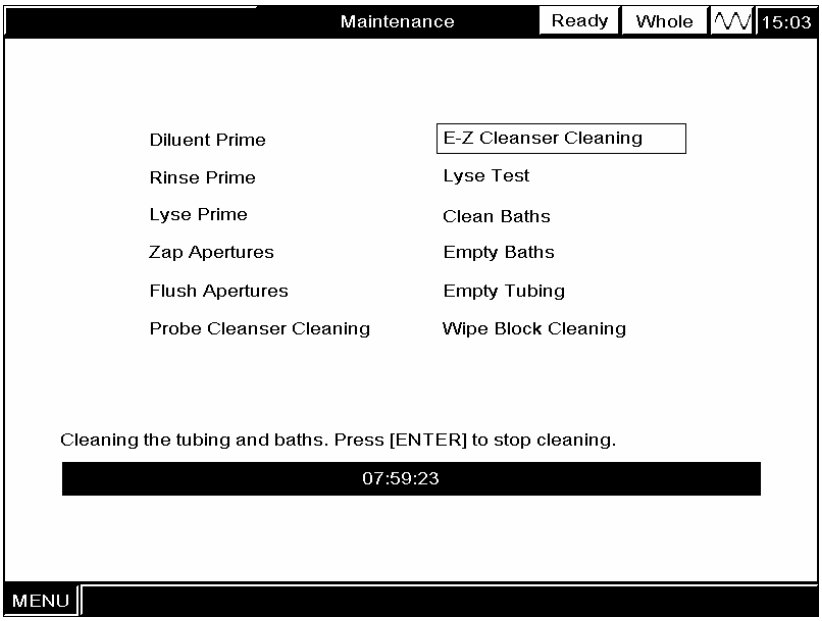


Figure10-13 E-Z cleaning

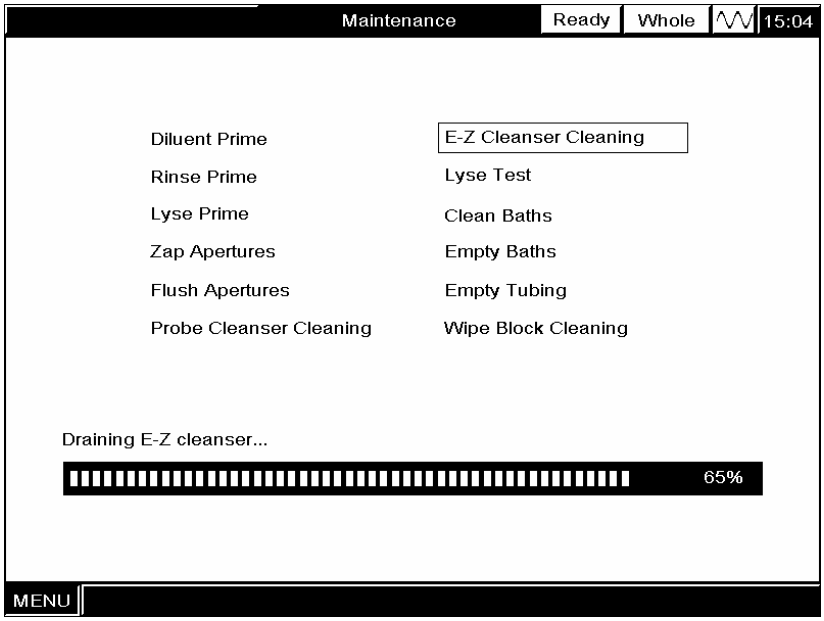


Figure10-14 Draining the baths and fluidic lines

10.3.8 Lyse Test

- **Samples, controls, calibrators and waste are potentially infectious. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them in the laboratory.**

In case of any abnormal WBC counts or histograms, you can perform the "**Lyse Test**" procedure to check whether the lyse can be dispensed properly.
Follow the steps given below to do so:

1. Push the right door latch in the direction indicated in Figure10-15.

Figure10-15

2. Lift up the front panel latch as indicated in Figure10-16 and open the front panel.

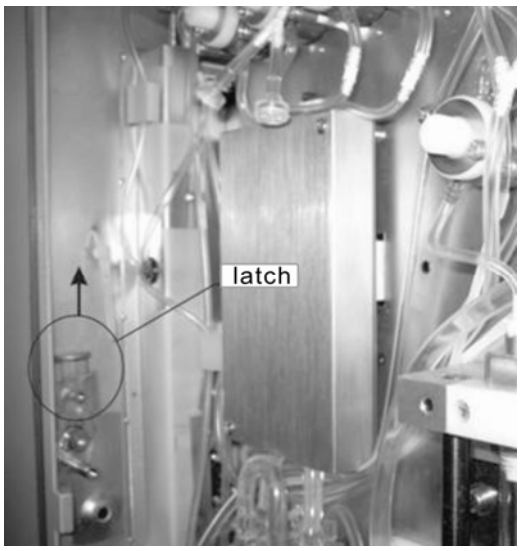


Figure10-16

3. Remove the screws fixing the shielding box of the bath and lift the shielding box, as Figure10-17 shows.

Figure10-17 Shielding box

4. Remove the shielding box to expose the bath, as Figure10-18 shows.

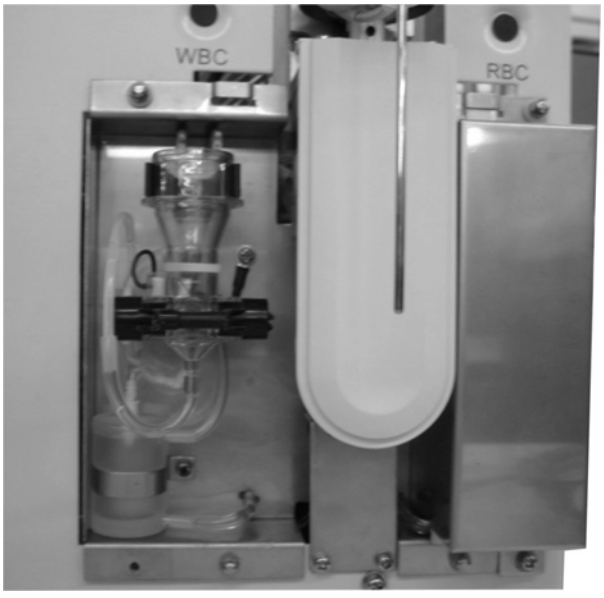


Figure10-18 WBC bath

5. At the "**Maintenance**" screen, ***SELECT*** "**Lyse Test**". Press [ENTER] and the analyzer will automatically drain the WBC bath and then dispense 2ml of lyse into the WBC bath.
6. Check the scale to see whether the lyse has reached the expected line (the first from bottom).If so, press [ENTER] and the analyzer will automatically flush the bath and dispense lyse and the test is done.
7. If not, repeat steps 5 and 6 several times. If all the tries have failed, check whether the lyse has run out or the lyse pickup tube is not properly connected to this analyzer. If the lyse is still enough and the tube is well connected to the analyzer, contact the Mindray or your local distributor for repair.

10.3.9 Cleaning Baths

If you suspect the baths are contaminated, follow the steps given below to perform the "**Clean Bath**" procedure:

1. At the "Maintenance" screen, ***SELECT*** "Clean Baths".
2. Press [ENTER] to start the procedure.

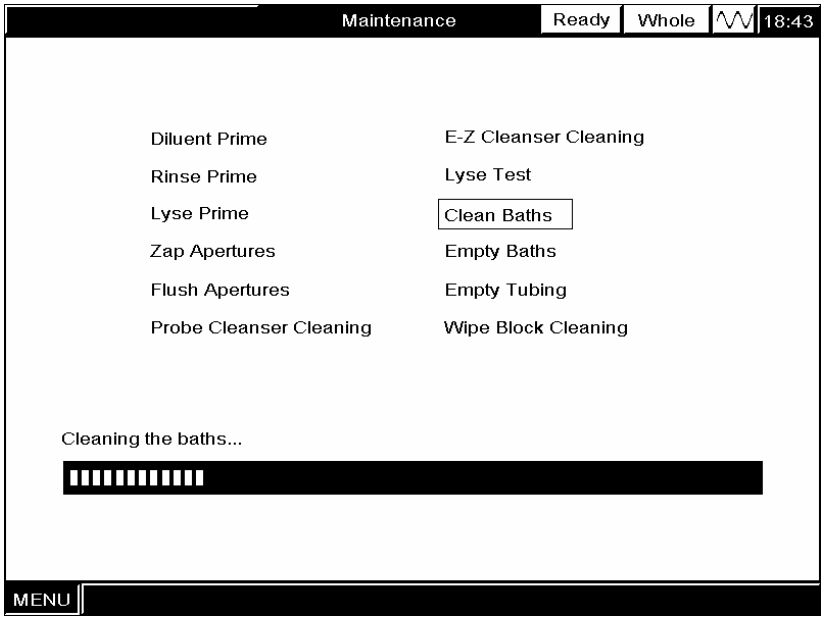


Figure10-19 Cleaning the baths

3. When the cleaning is done, the screen displays "**Clean Baths End**".

10.3.10 Empty Baths

When at three or more of the WBC, RBC, PLT and HGB results are abnormal, you may do the "**Empty Baths**" procedure to find out the reason.
Follow the steps below to do so:

1. Do steps 1-5 of the "**Lyse Test**" to expose the baths.
2. At the "**Maintenance**" screen, ***SELECT*** "**Drain Baths**" to drain the baths.

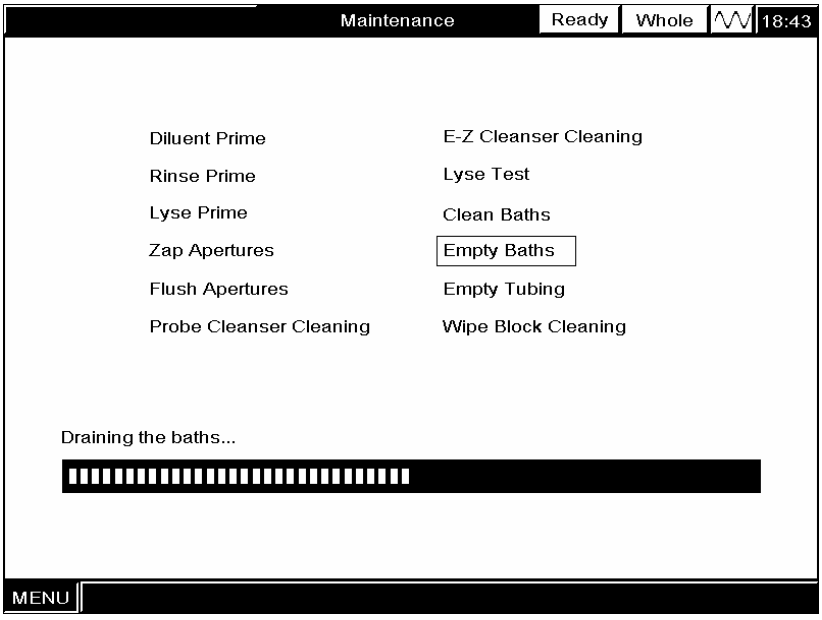


Figure10-20 Draining the baths

3. When the draining is done, check the baths and the tubing below them for residual fluid. If there is no fluid, press [ENTER] to prime the baths with diluent, as Figure10-21 shows. When the priming is done, the screen displays "**Empty Baths End**".

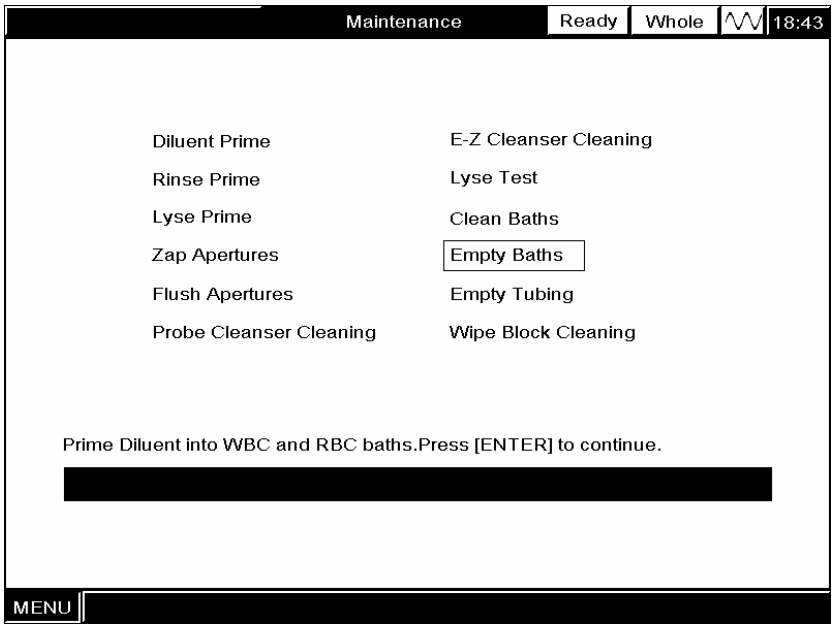


Figure10-21 Priming the baths with diluent

If there is fluid left, turn off the analyzer and call Mindray customer service department or your local distributor for assistance.

10.3.11 Empty Tubing

- **Samples, controls, calibrators and waste are potentially infectious. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them in the laboratory.**

NOTE

- **Be sure to do the "Empty Tubing" procedure before relocating the analyzer.**

If this analyzer is not to be used for a long time or it is to be maintained, be sure to perform the "**Empty Tubing**" procedure to drain the fluidic lines.
Follow the steps given below to do so：

1. At the "**Maintenance**" screen, press the appropriate arrow keys ([←][→] [↑][↓]) to move the cursor to "**Empty Tubing**".
2. Follow the displayed instructions to remove the diluent, rinse and lyse pickup tubes from this analyzer and then press [ENTER] to start the draining process, Figure10-22.

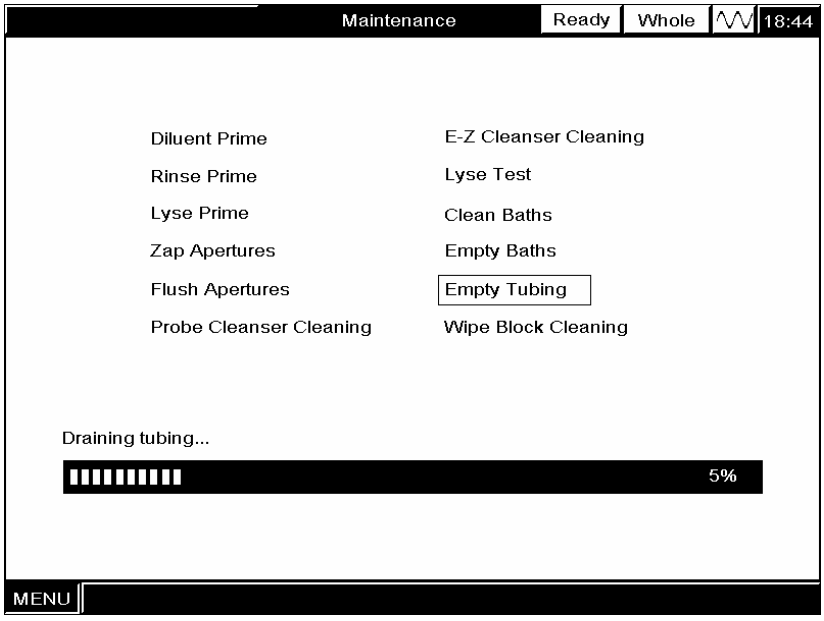


Figure10-22 Draining the fluidic lines

3. When the draining is done, the screen will display "**Turn off this analyzer**" and you should turn off this analyzer as instructed.

10.3.12 Wipe Block Cleaning

After being used for a long time, the bottom of the probe wipe may be contaminated by blood and the inside of wipe may also be contaminated by the dirt sucked in. So you need to clean the probe wipe regularly.

Follow the steps given below to do so:

1. At the "**Maintenance**" screen, ***SELECT*** "**Clean wipe block"**.
2. Present the probe cleanser to the sample probe and press [ENTER] to aspirate the cleanser. When you hear the beep and the sample probe is out of the bottle, remove the cleanser.
3. Push the right door latch in the direction indicated in Figure10-23.

Figure10-23

4. Lift up the front panel latch as indicated in Figure10-24 and open the front panel.

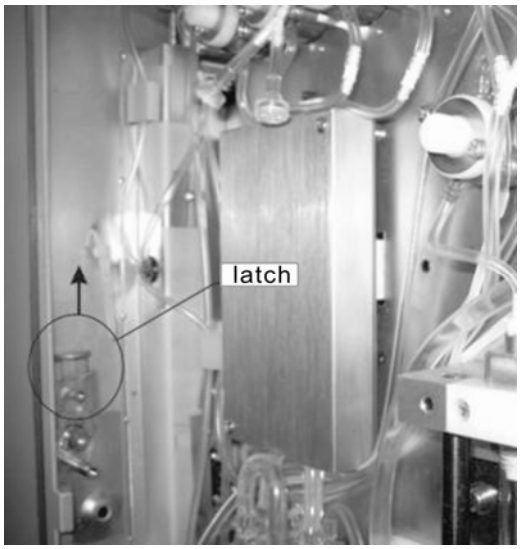


Figure10-24

5. Follow the instructions displayed on the screen to place an empty cup, whose diameter should be no less than 8cm, below the sample probe.
6. Press [ENTER] to soak the wipe block with the aspirated cleanser. The soaking progress will be displayed on the screen, as Figure10-25 shows.

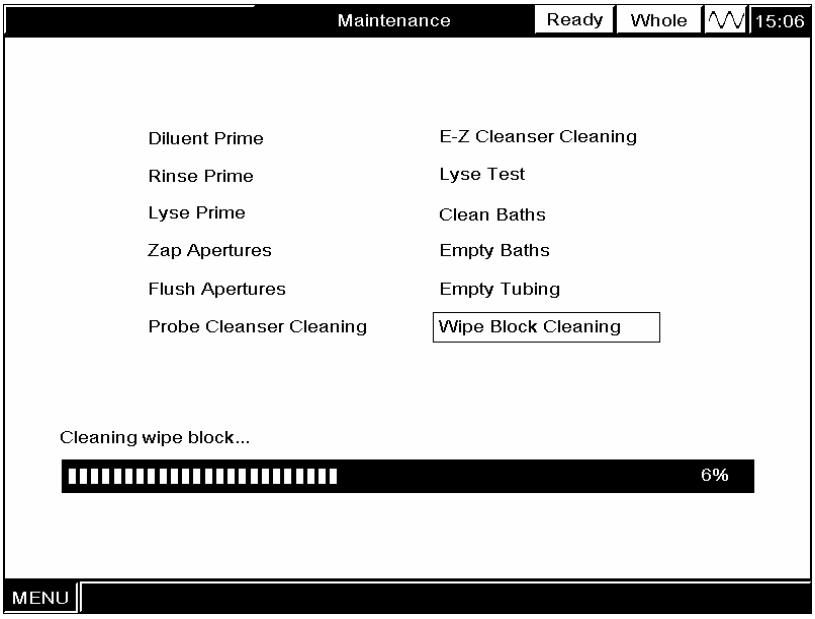


Figure10-25 Cleaning wipe block

NOTE

- **Spills are possible during the soaking process. Keep a minimum 30cm distance from the analyzer.**

7. When the soaking is done, wipe the bottom of the wipe block with a probe cleanser-dipped cloth that does not leave debris.
8. Press [ENTER] to flush the block and the interior of the probe and the flushing progress is displayed on the screen as Figure10-26 shows .
9. After the flushing is done, the screen returns to the initial state.

When the accumulated analyzed whole blood samples reach 2,000, or prediluted samples reach 4,000, a message box will pop up to remind to clean the probe wipe, as Figure10-27 shows. ***CLICK*** "**Enter**" to do the procedure; ***CLICK*** "**Cancel**" to abort the procedure.

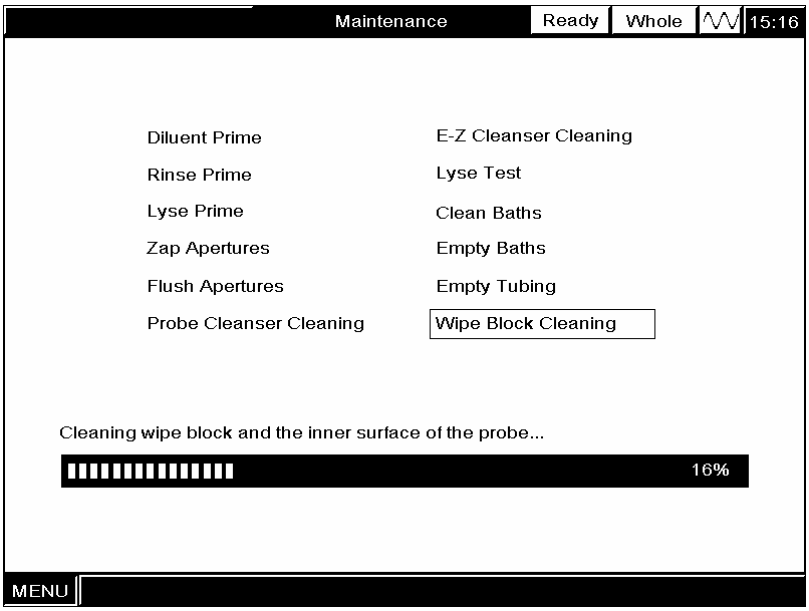


Figure10-26 Washing interior of the probe wipe and sample probe

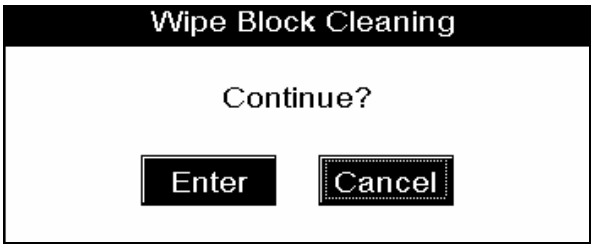


Figure10-27 A "Wipe Block Clean" message box

10.4 Using the "System Status" Program

The items displayed in the "**System Status**" screen reflect how the analyzer is functioning and contribute significantly to diagnosing analyzer errors. You may follow the instructions given below to check those items.

Press [MENU] to enter the system menu. ***SELECT*** "**Service**" → "**System Status**" (Figure10-28) to enter the "**System Status**" screen (Figure10-29).

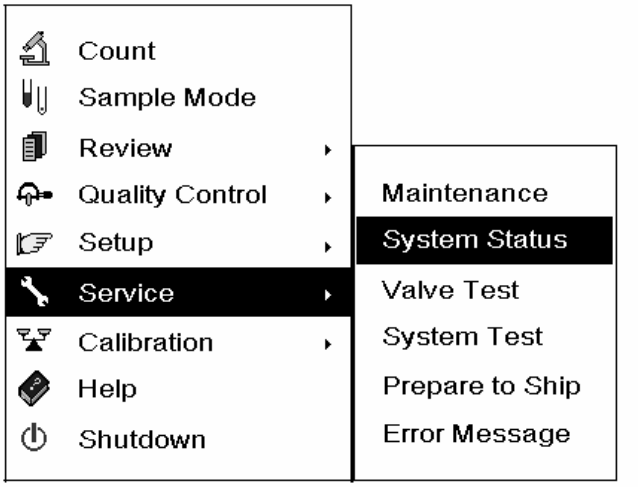
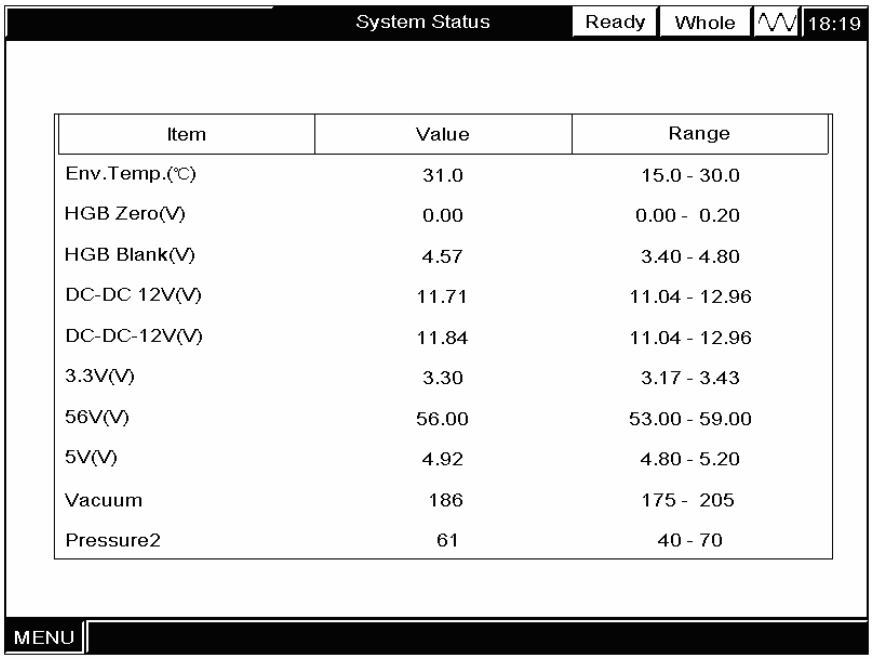


Figure10-28 System menu



Item	Value	Range
Env.Temp.(℃)	31.0	15.0 - 30.0
HGB Zero(V)	0.00	0.00 - 0.20
HGB Blank(V)	4.57	3.40 - 4.80
DC-DC 12V(V)	11.71	11.04 - 12.96
DC-DC-12V(V)	11.84	11.04 - 12.96
3.3V(V)	3.30	3.17 - 3.43
56V(V)	56.00	53.00 - 59.00
5V(V)	4.92	4.80 - 5.20
Vacuum	186	175 - 205
Pressure2	61	40 - 70

Figure10-29 "**System Status**" **screen**

Note that you can only view the displayed status items without changing them. If any of the displayed item exceeds the given range, see **Chapter 11 Troubleshooting** for solutions.

Press [MENU] to exit to the system menu and the screen will display "**Resetting**" and the system menu will pop up later.

10.5 Using the "Valve Test" Program

Malfunctioning valves will lead to fluidic system malfunctions. Therefore, testing the valves is a major way to remove fluidic errors.

Press [MENU] to enter the system menu. ***SELECT*** "**Service → Valve Test**" (Figure10-30) to enter the "**Valve Test**" screen (Figure10-31).

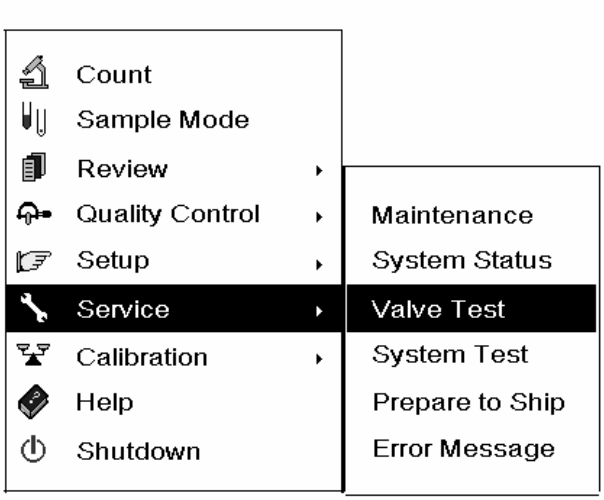


Figure10-30 System menu

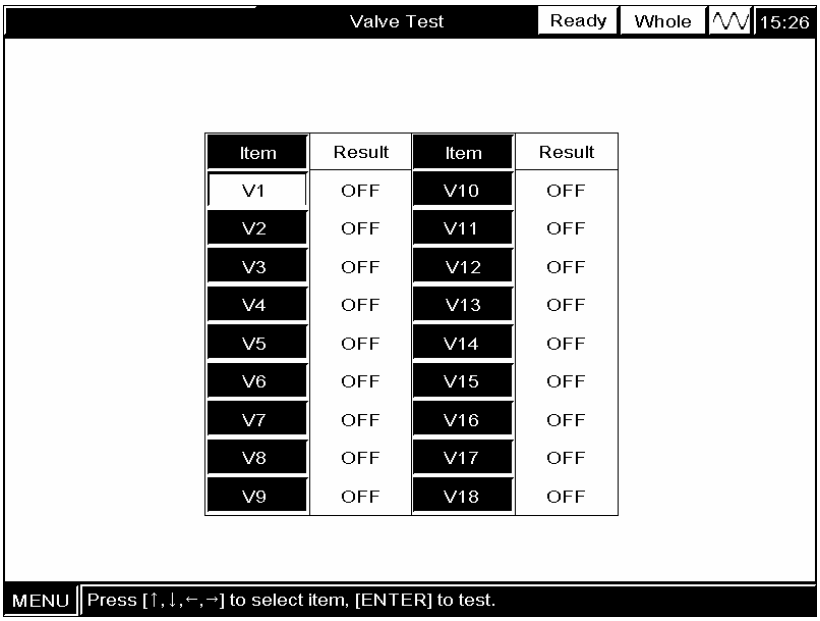


Figure10-31 "Valve Test" screen

SELECT the valve you want to check and press [ENTER] to test it. If the valve goes through the Off-On-Off sequence without making any abnormal sound, it passes the test. Otherwise, something may be wrong with the valve.

10.6 Using the "System Test" Program

Press [MENU] to enter the system menu. ***SELECT*** "**Service → System Test**" (Figure10-32) to enter the "**System Test**" screen (Figure10-33), where 19 test items are available. Note that you need to enter the administrator password to test the motors.

SELECT the desired item to perform the corresponding test. The test result will be displayed later. In case of any abnormal test result, see **Chapter 11 Troubleshooting Your Analyzer** for solutions and if necessary, contact Mindrayor your local distributor for assistance.

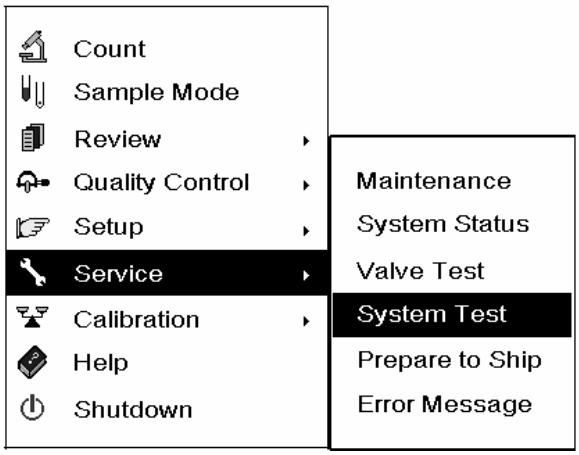


Figure10-32 System test

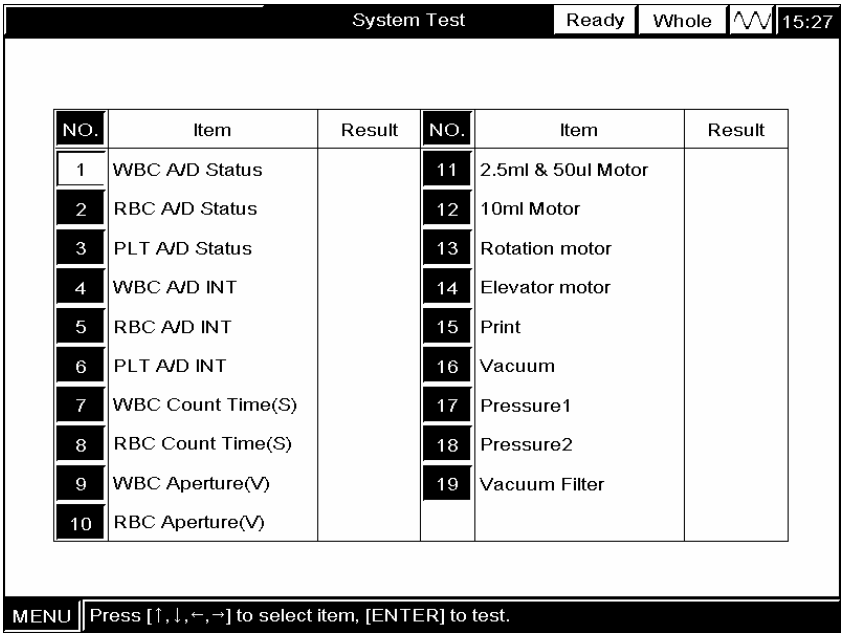


Figure10-33 System test screen

Press [MENU] to exit to the system menu and the screen will display "**Resetting**" and the system menu will pop up later.

10.7 Using the "Prepare to ship" Program

Use the "**Prepare to ship**" program to prepare your analyzer for a prolonged period of non-use or for shipping.

Press [MENU] to enter the system menu. ***SELECT*** "**Service→Prepare to ship**"(Figure10-34) to enter the "**Prepare to Ship**" screen (Figure10-35).

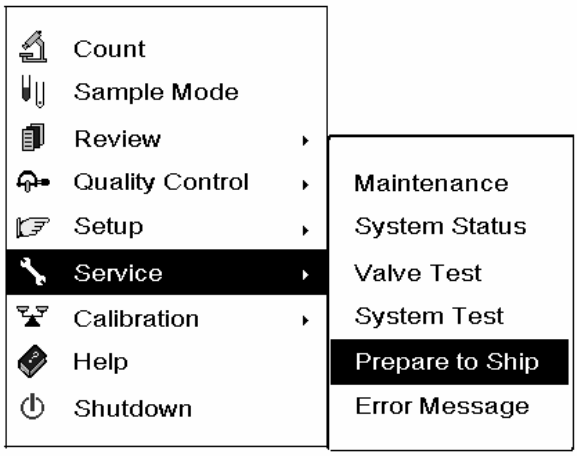


Figure10-34 System menu

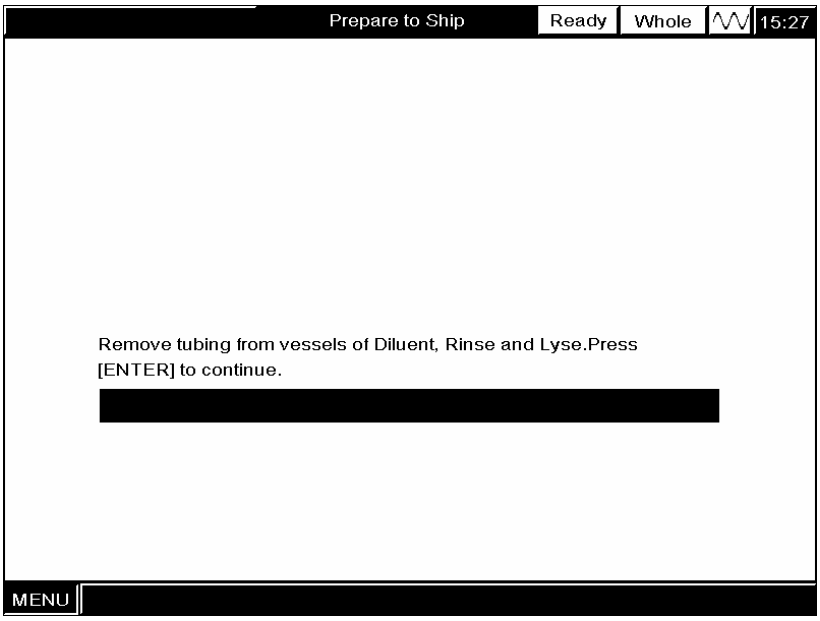


Figure10-35 "Prepare to Ship" screen

Follow the steps below to do so:

1. Remove the diluent, rinse and lyse pickup tubes from their containers and press [ENTER].

   A message box will pop up to confirm the operation, as Figure10-36 shows.

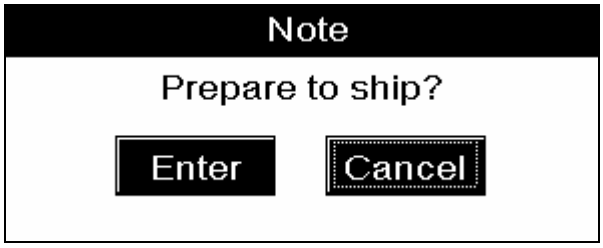


Figure10-36 A message box to confirm the operation

2. ***CLICK*** "**Enter**" to proceed with the operation.
3. The analyzer starts to drain the fluidic lines and the progress is displayed on the screen, as Figure10-37 shows.

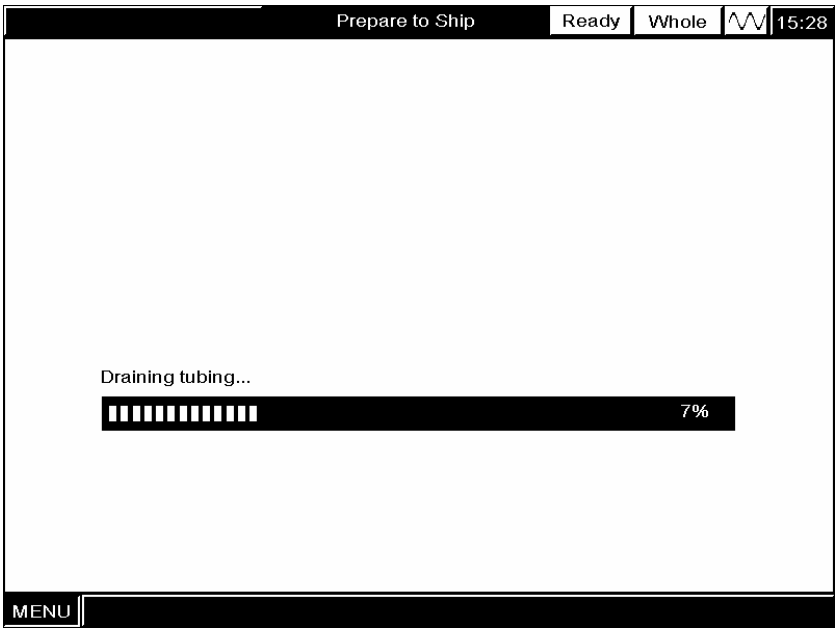


Figure10-37 Draining fluidic lines

4. When the draining is done, place the diluent, rinse and lyse pickup tubes into a container filled with distilled water and press [ENTER], as the Figure10-38 shows.

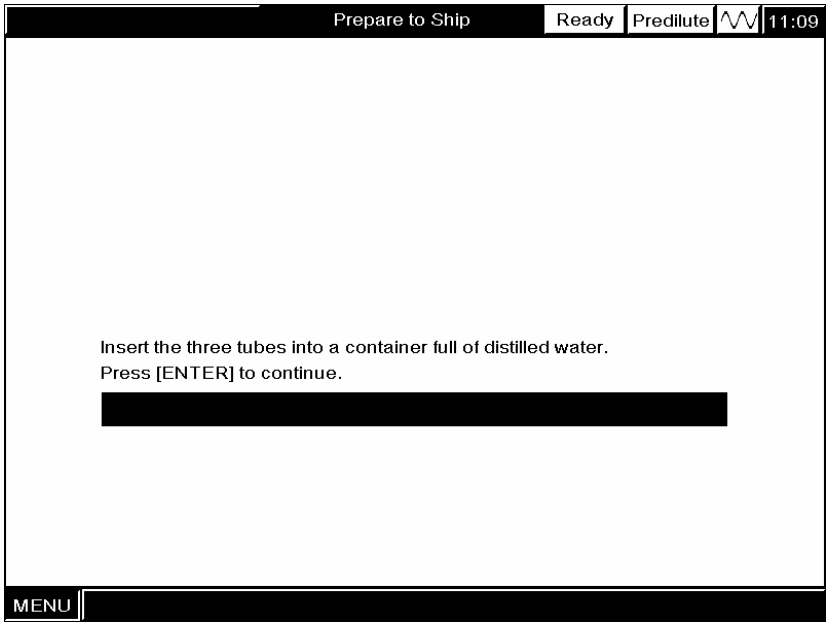


Figure10-38 Washing the analyzer

5. When the washing is done, remove the diluent, rinse and lyse pickup tubes from the distilled water and press [ENTER] to drain the fluidic lines.
6. When the draining is done and the screen displays "**You can turn off the analyzer now**", turn off the analyzer as instructed.
7. Wipe the analyzer dry and wrap it up.

10.8 Using the "Error Message" Program

The analyzer can store maximum 1,000 latest error messages. When the maximum number has reached, the latest overwrites the earliest.

Press [MENU] to enter the system menu. ***SELECT*** "**Service → Error Message**" (Figure10-39) to enter the "**Error Message**" screen (Figure10-40).

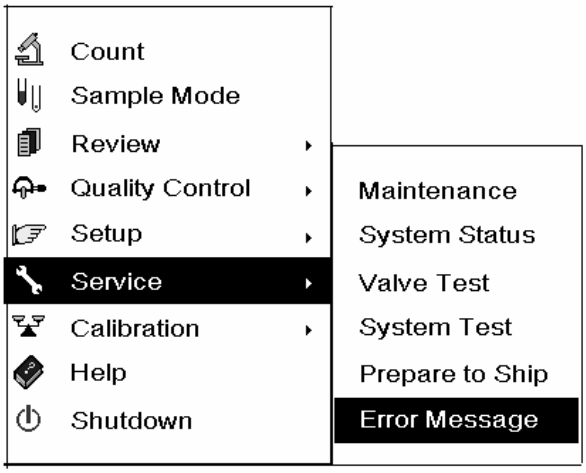


Figure10-39 System menu

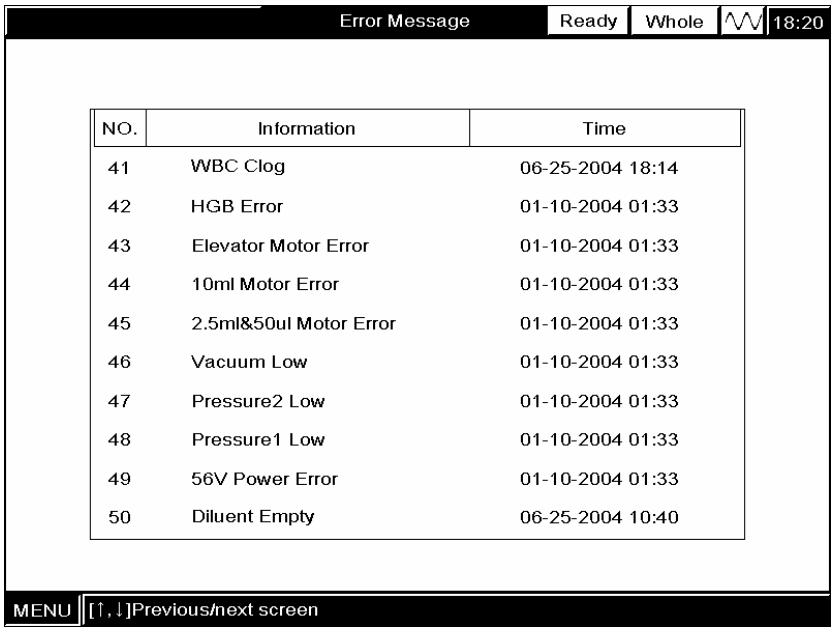


Figure10-40 "Error message" screen

Press [↑] or [↓] to browse the error messages. Press [PRINT] to print out the displayed error messages.

For the displayed error messages, see **Chapter 11 Troubleshooting Your Analyzer** for solutions.

Press [MENU] to exit the "**Error Message**" screen.

10.9 Calibrating Sample Probe Position

- **Samples, controls, calibrators and waste are potentially infectious. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them in the laboratory.**

⚠ WARNING

- **The sample probe tip is sharp and may contain biohazardous materials. Exercise caution to avoid contact with the probe when working around it.**

The relative position between the sample probe and probe wipe block has influence on the analysis results. In the accessory box, there is a sample probe localizer, as Figure10-41 shows. You need to use the localizer to adjust the position of the sample probe if you have replaced wipe block, or observed motor error, or wrong analysis result. Also, as required by regular maintenance, you should use the localizer to adjust the position of the sample probe monthly.

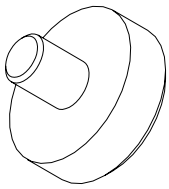


Figure10-41 Sample probe localizer

Follow the steps below to do so:

1. ***SELECT*** "**Setup** → **Password**" and enter the administrator password (3000);
2. Push the right door latch in the direction indicated in Figure10-42;

Figure10-42

3. Lift up the front panel latch as indicated in Figure10-43 and open the front panel;

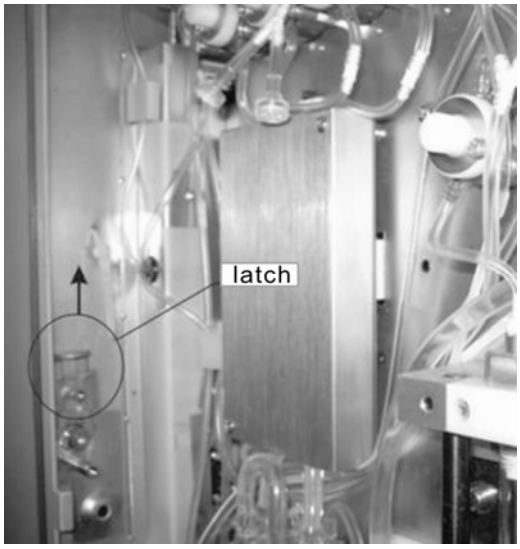


Figure10-43

4. ***SELECT*** "**Service**" →"**System Test**" to enter the "**System Test**" screen and ***SELECT*** "**Elevator motor**";

5. Press [↑] to move the sample probe to its highest position, as Figure10-44 shows;

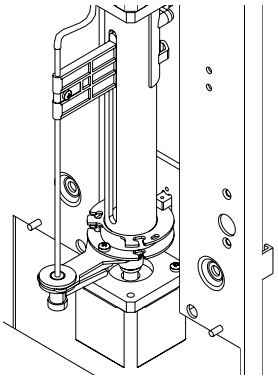


Figure10-44

6. Loose the retaining screw by a screwdriver, as Figure10-45 shows;

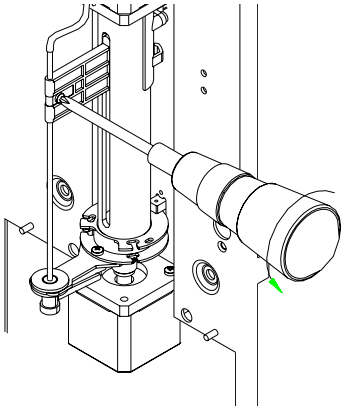


Figure10-45

7. Remove the probe from the wipe block and insert the localizer into the wipe block from the bottom, as Figure10-46 shows;

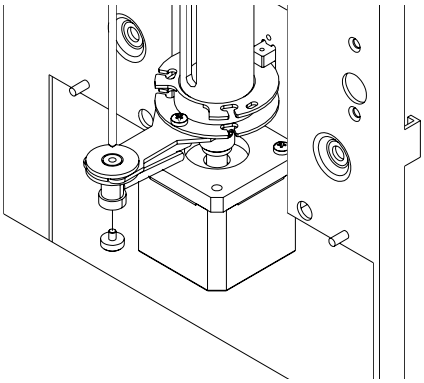


Figure10-46

8. Insert the probe into the wipe block until it reaches the localizer, as Figure10-47 shows;

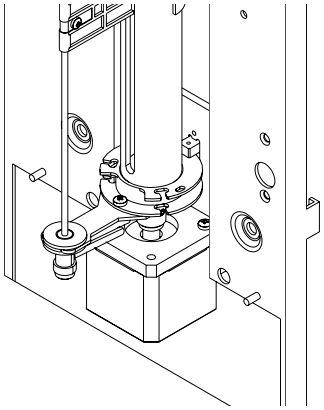


Figure10-47

9. Tighten the fixing screws and put away the localizer to finish the work.

10.10 Replacing the Probe Wipe.

- **Samples, controls, calibrators and waste are potentially infectious. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them in the laboratory.**

⚠ WARNING

- **The sample probe tip is sharp and may contain biohazardous materials. Exercise caution to avoid contact with the probe when working around it.**

To replace the probe wipe：

1. Refer to **Chapter 10.9** and do the steps 1 – 6;
2. Pull the loosen probe wipe upward to remove the wipe block and disconnect the tubes from the wipe block (pay attention to the correspondence between the tubes and the connectors), as Figure10-48 shows;

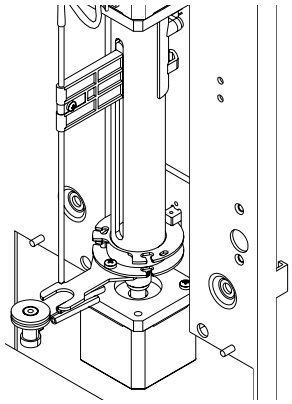


Figure10-48

3. Install a new block and connect the tubing end with the black marking to the connector below the block;
4. Refer to **Chapter 10.9** and do the steps 7 - 9 to fix the sample probe.

10.11 Replacing the Filter of the Vacuum Chamber

You need to replace the filter of the vacuum chamber when there is an air filter error. Follow the steps below to do so:

1. Push the right door latch in the direction indicated in Figure10-49;

Figure10-49

2. Find the filter shows in Figure10-50;

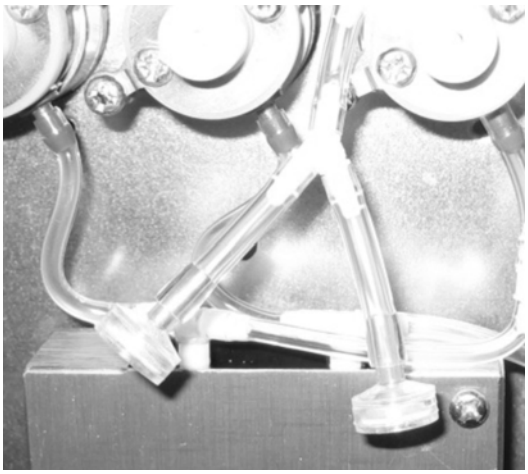


Figure10-50 Vacuum filter

3. Remove the filter and take a new one from the accessory kit and install it.

10.12 Using the [Flush] key

Press the [Flush] key to unclog the apertures when the analyzer alarms you for clogged WBC or RBC aperture.

10.13 Using the [Startup] key

Press the [Startup] key to flush the fluidic lines and check the background.

11 Troubleshooting Your Analyzer

11.1 Introduction

The BC-3000 Plus continuously monitors the status of the system and displays pertinent information in the upper left corner of the "**Count**" screen (the Error Message area). If a problem is detected, the Error Message area displays the corresponding error message. This chapter contains information that is helpful in locating and correcting problems that may occur during operation of your analyzer.

NOTE

- **This chapter is not a complete service manual and is limited to problems that are readily diagnosed and/or corrected by the user of the analyzer. If the recommended solution fails to solve the problem, contact Mindray customer service department or your local distributor.**

⚠ WARNING

- **Unless otherwise instructed, always turn off the power before trying to fix the error.**

- **Samples, controls, calibrators and waste are potentially infectious. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them in the laboratory.**

11.2 Errors without available error messages

Error	Possible Cause(s)	Recommended Action
The analyzer cannot be turned on.	1. The power cord is broken or not well connected; 2. The fuse is broken; 3. The power outlet has no electricity.	1. Check the power cord connection; 2. Check the fuse; 3. Check the electrical outlet.
Liquid drips from analyzer inside.	Damaged pump hose or blocked filter.	1. Turn off the power and wipe the analyzer dry. 2. Call Mindray customer service department or your local distributor for assistance.
Recorder does not work.	1. Recorder paper is jammed; 2. Something is wrong with the circuit.	1. Remove the jammed paper. 2. If the problem remains, turn off the analyzer and turn it on again in 10 seconds.

11.3 Errors indicated by error messages

The analyzer can provide 41 error messages. See the tables below for the error messages and their probable causes and recommended action. If the problem still remains after you have tried the recommended solutions, contact Mindray customer service department or your local distributor.

11.3.1 Pressure errors

Error Message	Possible Cause(s)	Recommended Action
Pressure 2 Low	The pressure inside the pressure chamber does not reach the expected value within the given time	1. Enter the "**Service → System Test**" screen and test the "**Chamber Pressure**" as instructed in **Chapter 10.6.** The error will be removed if the test result is normal; 2. If the problem remains, contact Mindray customer service department or your local distributor.
Vacuum Low	The vacuum degree does not reach the expected value within the given time.	1. Check the tubes connected to the back of the analyzer and make sure they are not pressed; 2. If the tubes are fine, enter the "**Service → System Test**" screen and test the "**Vacuum**" as instructed in **Chapter 10.6**. The error will be removed if the test result is normal; 3. If the problem remains, contact Mindray customer service department or your local distributor.

Pressure 1 low	The pressure inside the vacuum chamber does not reach the expected value within the given time.	1. Enter the "**Service → System Test**" screen and do the "**Pressure 1**" procedure as instructed in **Chapter 10.6**. The error will be removed if the test result is normal; 2. If the problem remains, contact Mindray customer service departmentor your local distributor.
Vacuum Filter Error	The air inside the vacuum chamber is not extracted within the given time.	1. Enter the "**Service → System Test**" screen and test the "Vacuum" as instructed in Chapter 10.6. The error will be removed if the test result is normal; 2. If the problem remains, change a new filter; 3. If the problem remains, contact Mindray customer service department or your local distributor.

11.3.2 Reagent errors

Error Message	**Possible Cause(s)**	**Recommended Action**
Lyse Empty	No lyse or a malfunctioning level transducer.	1. Check if the lyse has run out and if so; 2. Change a new container of lyse as instructed in **Chapter 4.4.2**; 3. If the problem remains, contact Mindray customer service department or your local distributor.
Diluent Empty	No diluent or a malfunctioning level transducer.	1. Check if the lyse has run out, and if so; 2. Change a new container of diluent

		as instructed by **Chapter 4.4.2**; 3. If the problem remains, contact Mindray customer service departmentor your local distributor.
Rinse Empty	No rinse or a malfunctioning level transducer.	1. Check if the rinse has run out, and if so, 2. Change a new container of rinse as instructed by **Chapter 4.4.2**; 3. If the problem remains, contact Mindray customer service department or your local distributor.
Rinse Expiry	Expired rinse or wrong expiration setting	1. Check if the rinse has expired. If so, change a new container of rinse as instructed by **Chapter 4.4.2**; 2. If not, reset the expiration date as instructed in **Chapter 5.10.1**.
Diluent Expiry	Expired diluent or wrong expiration setting	1. Check if the diluent has expired. If so, change a new container of diluent as instructed by **Chapter 4.4.2**; 2. If not, reset the expiration date as instructed in **Chapter 5.10.1**.
Lyse Expiry	Expired lyse or wrong expiration setting	1. Check if the lyse has expired. If so, change a new container of lyse as instructed by **Chapter 4.4.2**; 2. If not, reset the expiration date as instructed in **Chapter 5.10.1**.

11.3.3 Hardware errors

Error Message	Possible Cause(s)	Recommended Action
Real-Time Clock Error	1. Someone tempered with the on-board battery off the board; 2. Something is wrong with the on-battery (poor contact, dead battery, etc.); 3. Damaged real-clock chip.	1. Enter "**Setup → Date & Time**" screen and reset the time as instructed by **Chapter 5.7**. Restart the analyzer after the adjustment and the time should be correct; 2. If the problem remains, contact Mindray customer service department or your local distributor.
10ml Motor Error	1. Pressed or blocked tubes; 2. Poor contact of the signal line; 3. Damaged motor; 4. Poor connection between the drive board and the CUP board; 5. Malfunctioning photo coupler.	1. Check if the tubes at the back of the analyzer is pressed or blocked; 2. If not, enter the "**Service → System Test**" screen and check the motor as instructed in **Chapter 10.6**. The error will be removed if the test result is normal; 3. If the problem remains, contact Mindray customer service department or your local distributor.
2.5ml&50ul Motor Error	1. Poor contact of the signal line; 2. Damaged motor; 3. Poor connection between the drive board and the CUP board; 4. Malfunctioning photo coupler;	1. Enter the "**Service → System Test**" screen and check the motor as instructed in **Chapter 10.6**. The error will be removed if the test result is normal. 2. If the problem remains, contact Mindray customer service department or your local distributor.
Elevator Motor Error	1. Jammed sample probe;	1. Open the front panel and check if

	2. Poor contact of the signal line; 3. Damaged motor; 4. Poor connection between the drive board and the CUP board; 5. Malfunctioning photo coupler.	the sample probe is jammed; 2. Enter the "**Service → System Test**" screen and check the motor as instructed in Chapter 10.6. The error will be removed if the test result is normal; 3. If the problem remains, contact Mindray customer service department or your local distributor.
Rotation Motor Error	1. Jammed sample probe; 2. Poor contact of the signal line; 3. Damaged motor; 4. Poor connection between the drive board and the CUP board; 5. Malfunctioning photo coupler.	1. Open the front panel and check if the sample probe is jammed; 2. Enter the "**Service → System Test**" screen and check the motor as instructed in **Chapter 10.6**. The error will be removed if the test result is normal; 3. If the problem remains, contact Mindray customer service department or your local distributor.
WBC Interrupt Error	Something is wrong with the A/D part of the CPU board.	1. Enter the "**Service → System Test**" screen and check the WBC AD interrupt as instructed in **Chapter 10.6**; 2. The error will be removed if the test result is normal; 3. If the problem remains, contact Mindray customer service department or your local distributor.
RBC Interrupt Error	Something is wrong with the A/D part of the CPU board.	1. Enter the "**Service → System Test**" screen and check the RBC AD interrupt as instructed in

		Chapter 10.6; 2. The error will be removed if the test result is normal; 3. If the problem remains, contact Mindray customer service department or your local distributor.
PLT Interrupt Error	Something is wrong with the A/D part of the CPU board.	1. Enter the "**Service → System Test**" screen and check the PLT AD interrupt as instructed in **Chapter 10.5**; 2. The error will be removed if the test result is normal; 3. If the problem remains, contact Mindray customer service department or your local distributor.

11.3.4 Power supply errors

Error Message	Possible Cause(s)	Recommended Action
DC/DC Error	Something is wrong with the internal DC power supplies.	1. Enter the "**Service**" → "**System Status**" screen and record the "**DC-DC 12V**" and "**DC-DC -12V**" values; 2. Shut down the analyzer and contact Mindray customer service department or your local distributor.
5V Power Error	Something is wrong with the power board.	1. Enter the "**Service → System Status**" screen and record the "**5V**" voltage; 2. Shut down the analyzer and contact Mindray customer service department or your local distributor.
3.3V Power Error	Something is wrong with the 5V power supply.	1. Enter the "**Service → System Status**" screen and record the

		"**3.3V**" voltage; 2. Shut down the analyzer and contact Mindray customer service department or your local distributor.
56V Power Error	Something is wrong with the power board.	1. Enter the "**Service → System Status**" screen and record the "**56V**" voltage; 2. Shut down the analyzer and contact Mindray customer service department or your local distributor.

11.3.5 Measurement errors

Error Message	Possible Cause(s)	Recommended Action
Background Abnormal	1. Contaminated diluent, diluent lines or bath (s); 2. Expired diluent; 3. The tubes at the back of the analyzer are pressed.	1. Check if the diluent is contaminated or expired; 2. Check if the tubes connected at the back of the analyzer is pressed; 3. Enter the "**Count**" screen and press [STARTUP] (or [F3] of the external keyboard) to do the startup procedure; 4. If the problem remains, enter the "**Service → Maintenance**" screen and do the probe cleanser cleaning procedure as instructed in **Chapter 10.3.6.** When the procedure is finished, return to the "**Count**" screen and do the background check again; 5. If the problem remains, contact Mindray customer service

		department or your local distributor.
HGB Error	HGB blank voltage within 0 V - 3.2 V or 4.9 V - 5 V.	1. Do the "**Probe Cleanser Cleaning**" procedure as instructed in **Chapter 10.3.6.**; 2. If the problem remains, adjust the HGB gain as instructed by **Chapter 5.8.3** to set the voltage within 3.4 - 4.8V, preferably 4.5V; 3. If the problem remains, shut down your analyzer and contact Mindray customer service department or you local distributor.
HGB Adjust	HGB blank voltage within 3.2 V - 3.4 V or 4.8 V – 4.9 V.	1. Do the "**Probe Cleanser Cleaning**" procedure as instructed in **Chapter 10.3.6**; 2. If the problem remains, adjust the HGB gain as instructed by **Chapter 5.8.3** to set the voltage within 3.4 - 4.8V, preferably 4.5V; 3. If the problem remains, shut down your analyzer and contact Mindray customer service department or you local distributor.
WBC Clog	1. Clogged WBC aperture; 2. Inappropriate WBC count time setting; 3. Solenoid valve error.	1. Enter the "**Service → Maintenance**" screen. Zap and flush the aperture as instructed by **Chapter 10.3.4** and **10.3.5**; 2. Enter the "**Setup → Count Time**" screen and record the WBC count time. Then enter the "**Service → System Test**" screen and test the actual WBC count time as

		instructed by **Chapter 10.6**; 3. If the difference between the reference WBC count time and the actual WBC count time is less than 2 seconds, the error has been removed; 4. If not, enter the "Service" → "Maintenance" screen and do the probe cleanser cleaning procedure as instructed by **Chapter 10.3.6**; 5. Enter the "**Setup → Count Time**" screen and record the WBC count time. Then enter the "**Service → System Test**" screen and test the actual WBC count time as instructed by **Chapter 10.6**; 6. If the difference between the reference WBC count time and the actual WBC count time is less than 2 seconds, the error has been removed; 7. If the difference is still greater than 2 seconds but consistent, enter the "**Setup → Count Time**" and reset the WBC count time. Then enter the "**Service → System Test**" screen and test the actual WBC count time as instructed by **Chapter 10.6** to confirm the difference is less than 2 seconds. 8. If the problem remains, contact Mindray customer service department or your local distributor.

WBC bubbles	1. Diluent or rinse running out; 2. Loose tube connections; 3. Inappropriate WBC count time setting.	1. Check if the diluent or rinse has run out. If so, change a new container of diluent or rinse as instructed in **Chapter 4.4.2**; 2. Check the connection of the diluent and rinse pickup tube. If necessary, reconnect and tighten them as instructed by **Chapter 4.4.2**; 3. If the problem remains, adjust the WBC count time as instructed by **Chapter 5.3**; 4. If the problem remains, contact Mindray customer service department or your local distributor.
RBC clog	1. Clogged RBC aperture; 2. Inappropriate RBC count time setting; 3. Solenoid valve error.	1. Enter the "**Service → Maintenance**" screen. Zap and flush the aperture as instructed by **Chapter 10.2.4** and **10.2.5.**; 2. Enter the "**Setup → Count Time**" screen and record the RBC count time. Then enter the "**Service → System Test**" screen and test the actual RBC count time as instructed by **Chapter 10.6**; 3. If the difference between the reference RBC count time and the actual RBC count time is less than 2 seconds, the error has been removed; 4. If not, enter the "**Service → Maintenance**" screen and do the probe cleanser cleaning procedure as instructed by **Chapter 10.3.6**;

		5. Enter the "**Setup → Count Time**" screen and record the RBC count time. Then enter the "**Service → System Test**" screen and test the actual RBC count time as instructed by **Chapter 10.6.**; 6. If the difference between the reference RBC count time and the actual RBC count time is less than 2 seconds, the error has been removed. 7. If the difference is still greater than 2 seconds but consistent, enter the "**Setup → Count Time**" and reset the RBC count time. Then enter the "**Service → System Test**" screen and test the actual RBC count time as instructed by **Chapter 10.6** to confirm the difference is less than 2 seconds. 8. If the problem remains, contact Mindray customer service department or your local distributor.
RBC bubbles	1. Diluent or rinse running out; 2. Loose tube connections; 3. Inappropriate RBC count time setting.	1. Check if the diluent or rinse has run out. If so, change a new container of diluent or rinse as instructed in **Chapter 4.4.2**; 2. Check the connection of the diluent and rinse pickup tube. If necessary, reconnect and tighten them as instructed by **Chapter 4.4.2**; 3. If the problem remains, adjust the RBC count time as instructed by

		Chapter 5.3; 4. If the problem remains, contact Mindray customer service department or your local distributor.

11.3.6 External connection errors

Error Message	Possible Cause(s)	Recommended Action
Com Error	1. Communication cable not well connected; 2. Inappropriate communication settings.	1. Check if the communication cable is well connected; 2. Check the communication settings as instructed by **Chapter 5.6** and make sure they are the same with the host.
Barcode Com Error	Poor connection between the scanner and the analyzer.	1. Check if the analyzer is well connected to the analyzer; 2. If the problem remains, contact Mindray customer service department or your local distributor.
Barcode Error	1. Poor connection between the scanner and the analyzer; 2. Invalid bar-code.	1. Check if the analyzer is well connected to the analyzer; 2. Check if the bar-code is valid; 3. If the problem remains, contact Mindray customer service department or your local distributor.
Printer Offline	Poor connection between the printer and the analyzer.	Check if the printer is well connected to the analyzer.
Recorder Com Error	1. Poor connection between the recorder and the analyzer; 2. Damaged recorder.	Shut down the analyzer and contact Mindray customer service department.

Printer out of paper	Printer paper running out or not properly installed.	1. Check if there is printer paper; 2. Check if the printer paper is well installed.
Recorder out of paper	Recorder paper running out or not properly installed.	1. Check if the recorder paper has run out. If so, install the paper as instructed by Chapter 4.4.3; 2. Check if the recorder paper is properly installed. If not, re-install the paper as instructed by Chapter 4.4.3; 3. If the problem remains, contact Mindray customer service department or your local distributor.
Recorder too Hot	Recorder head too hot.	Stop using the recorder. If the problem repeats, contact Mindray customer service department.
Press Bar Up	Tension lever not replaced.	1. Press the tension lever as instructed in **Chapter 4.4.3**; 2. If the problem remains, contact Mindray customer service department or your local distributor.

11.3.7 Ambient temperature error

Error Message	**Possible Cause(s)**	**Recommended Action**
Ambient Temp. Abnormal	Abnormal ambient temperature or temperature transducer error.	1. Enter the "**Service → System Status**" screen to check the ambient temperature; 2. If the actual ambient exceeds the pre-defined ambient temperature, adjust the temperature. Otherwise, the analysis results may be

		unreliable; 3. If the actual temperature is within the pre-defined range and the problem remains, contact Mindray customer service department or your distributor.

11.3.8 Other errors

Error Message	Possible Cause(s)	Recommended Action
File Error	Something is wrong with the file system.	Shut down the analyzer and contact Mindraycustomer service department or your local distributor.
Dynamic Memory Error	Something is wrong with the system memory.	Shut down the analyzer and contact Mindray customer service department or your local distributor.

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B Specifications

B.1 Classification

According to the CE classification, the BC-3000 Plus is an In Vitro Diagnostic device.

B.2 Reagents

Diluent	M-30D DILUENT
Rinse	M-30R RINSE
Lyse	M-30CFL LYSE
E-Z Cleanser（Enzyme cleanser）	M-30E E-Z CLEANSER
Probe Cleanser	M-30P PROBE CLEANSER

B.3 Parameters

Table 12-1 Directly measured parameters and histograms

Parameter	Abbreviation	Default Unit
White Blood Cell or leukocyte	WBC	10^9/L
Red Blood Cell or erythrocyte	RBC	10^{12}/L
Hemoglobin Concentration	HGB	g/L
Platelet	PLT	10^9/L
WBC histogram	WBC Histogram	/
RBC histogram	RBC Histogram	/
PLT histogram	PLT Histogram	/

Table 12-2 Parameters derived from histograms

Parameter	Abbreviation	Default Unit
Lymphocyte percentage	Lymph%	%
Mid-sized cell percentage	Mid%	%
Granulocyte percentage	Gran%	%
Mean Corpuscular Volume	MCV	fL
Red Blood Cell Distribution Width Coefficient of	RDW-CV	%
Red Blood Cell Distribution Width Standard Deviation	RDW-SD	fL
Mean Platelet Volume	MPV	fL
Platelet Distribution Width	PDW	/

Table 12-3 Calculated parameters

Parameter	Abbreviation	Default Unit
Lymphocyte	Lymph#	10^9/L
Mid-sized cell	Mid#	10^9/L
Granulocyte	Gran#	10^9/L
Hematocrit	HCT	%
Mean Cell Hemoglobin	MCH	pg
Mean Cell Hemoglobin Concentration	MCHC	g/L
Mean Platelet Volume	PCT	%

B.4 Sampling Features

B.4.1 Sample volumes required for each analysis

Whole Blood Mode (vein blood) 13 μL

Prediluted Mode (capillary blood) 20 μL

B.4.2 Lyse used for every analysis

Whole blood 0.5 mL

Prediluted 0.36mL

B.4.3 Dilution rate

	WBC/HGB	RBC/PLT
Whole blood	1:308	1:44872
Prediluted	1:428	1:43355

B.4.4 Aperture size

	Diameter	Length
WBC	100 μm	70 μm
RBC	70 μm	65 μm

B.4.5 Throughput

Less than 1 minute / analysis

B.5 Performance specifications

B.5.1 Operating range

Parameter	Operating range
WBC (10^9/L)	0.0 - 999.9
RBC (10^{12}/L)	0.00 - 9.99
HGB (g/L)	0 - 300
MCV (fL)	0.0 - 250.0
PLT (10^9/L)	0 - 2999

B.5.2 Normal background

Parameter	Background result
WBC	≤ 0.3×10^9 / L
RBC	≤ 0.03×10^{12}/ L
HGB	≤ 1 g / L
HCT	≤ 0.5 %
PLT	≤ 10×10^9 / L

B.5.3 Linearity range

Parameter	Linearity range
WBC (10^9/L)	0.3 - 99.9
RBC (10^{12}/L)	0.20 - 8.00
HGB (g/L)	10 - 250
PLT (10^9/L)	10 - 999

B.5.4 Reproducibility

These reproducibility requirements applies only to the situation in which 11 normal-level controls have been run and the results of the 2nd to 11th runs are used to calculate the reproducibilities.

Parameter	Condition	Reproducibility（CV%）
WBC	7.0 - 15.0 × 10^9 / L	≤ 2.5
RBC	3.50 - 6.00 × 10^{12} / L	≤ 2.0
HGB	110 - 180 g/L	≤ 1.5
MCV	80.0 - 110.0 fL	≤ 0.5
PLT	150 - 500 × 10^9 / L	≤ 5.0

B.5.5 Carryover

Parameter	Carryover
WBC	≤ 0.5 %
RBC	≤ 0.5 %
HGB	≤ 0.5 %
PLT	≤ 1 %

B.6 Input/output device

NOTE

- **Be sure to use the specified devices only.**

B.6.1 Display

Color LCD, 10.2″, 800×600.

B.6.2 Keypad

23-key keypad.

B.6.3 Keyboard

PS/2 keyboard.

B.6.4 Bar-code scanner（optioanl）

TYSSO CCD-82 scanner.

B.6.5 Recorder

Built-in thermal recorder that supports two printing formats and auto printing.

B.6.6 Printer（optional）

EPSON LQ-300K+.

B.6.7 Interfaces

- A keyboard interface.
- Two RS-232 interfaces (maximum transmission distance 12 meters);
- A parallele port(for printer or floppy disk drive);
- A power supply for the floppy disk drive（only to be used with the power cable supplied by Mindray ）.

B.7 Power supply

- Voltage**:** AC 100 V – 240 V;
- Frequency: 50/60 Hz;
- Input power**:** 180 VA;
- Fuse**:** AC 250 V T4 A.

NOTE

- **Be sure to use the fuse of the specified type and rating.**

B.8 EMC Description

- The product is subject to the EMC test as required by EN61326:1997+A1 1998+A2 2001+A3 2003;
- EMS is compliance with experiment environment;
- EMC is compliance with Class A.

B.9 Sound

Maximal sound: 77 dB.

B.10 Operating environment

- Operating temperature: 15 ℃ - 35 ℃;
- Optimal operating temperature: 15 ℃ - 30 ℃;
- Relative humidity: 30 % - 85 %;
- Atmospheric pressure: 70 kPa - 106 kPa.

B.11 Storage environment

- Ambient temperature: -10 ℃ - 40 ℃
- Relative humidity: 10 % - 93 %
- Atmospheric pressure: 70 kPa - 106 kPa

B.12 Dimensions

Length	Width	Height
40 cm	39 cm	46 cm

B.13 Weight

21 kg

B.14 Contraindications

None.

C Precautions, Limitations and Hazards

C.1 Introduction

You will find the following symbols in this manual.

When you see…	Then…
⚠ WARNING	read the statement below the symbol. The statement is alerting you to an operating hazard that can cause personnel injury.
⚠ CAUTION	read the statement below the symbol. The statement is alerting you to a possibility of analyzer damage or unreliable analysis results.
NOTE	read the statement below the symbol. The statement is alerting you to information that requires your attention.
	read the statement below the symbol . The statement is alerting you to a potentially biohazardous condition.

C.1.1 Installation Requirements

All the space, power and environmental requirements listed in Chapter 4 and Appendix B must be met. Establishing and maintaining prope grounding cannot be overemphasized.

C.1.2 Limitations

Whenever the results are outside the normal limits, it is recommended that the laboratory following whatever written protocol is in place for validating results.

If an error occurs, the analyzer displays the corresponding error message In case of errors related to the fluidic system (such as clogging or bubbles), it is recommnended that you re-run the sample after removing the error.

If the PLT value is less than 100×10^9 / L, it is recommended the result be verified by a microscope.

C.1.3 Maintenance

The maintenance instructions in Chapter 10 decribe corrective and preventive procedures that must be followed to ensure proper operation and performance of your analyzer.

C.2 Warnings

⚠ WARNING

- **It is important for the hospital or organization that employs this equipment to carry out a reasonable service/maintenance plan. Neglect of this may result in machine breakdown or injury of human health.**
- **Make sure the analyzer is properly grounded.。**
- **Before turning on the analyzer, make sure the input voltage meets the above requirements.**
- **When moving the analyzer, be sure to face the front of the analyzer and carry it from the bottom with hands!**
- **The reagents are irritating to eyes, skin and diaphragm. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them in the laboratory.**
- **If the reagents accidentally spill on your skin, wash them off with plenty of water and if necessary, go see a doctor; if the reagents accidentally spill into your eyes, wash them off with plenty of water and immediately go see a doctor.**
- **Do not place the analyzer in a flammable or explosive environment.**
- **Be sure to dispose of reagents, waste, samples, consumables, etc. according to government regulations.**
- **Avoid direct contact with patient samples.**
- **The sample probe tip is sharp and may contain biohazardous materials. Exercise caution to avoid contact with the probe when working around it.**
- **To avoid personal injury, be sure to keep your clothes, hair and hand away from such moving parts as the sample probe.**
- **Only install a fuse of the specified type and rating.**

C.3 Cautions

⚠ CAUTION

- **Installation by personnel not authorized or trained by Mindray may damage your analyzer. Do not install your analyzer without the presence of Mindray-authorized personnel.**
- **Liquid ingression may damage the analyzer. Do not place any bottles on the analyzer.**
- **Do not connect or disconnect the printer, bar-code scanner or keyboard when the anlazyer is on.**
- **Improper installation of recorder paper may jam the paper and/or result in blank printouts.**
- **Do not re-use disposable products.**
- **When dispensing or aspirating liquids, remove the bottle or tube away only after the sample probe is out of it.**
- **Do not perform any maintenance procedures that are not described in this chapter. Performing unauthorized maintenance procedures can damage your analyzer.**
- **In case of problems not specified in this manual, contact Mindray customer service department or your local distributor for assistance.**
- **Only Mindray-supplied parts can be used for maintenance. For any questions, contact Mindray customer service department or your local distributor.**

C.4 Notes

NOTE

- **This equipment must be operated by skilled/trained medical professionals.**
- **Be sure to operate the analyzer strictly as instructed in this manual.**
- **This analyzer adopts a fixed decimal point. You can enter the digits without bothering to look for the [.] on the external keyboard.**
- **The purpose of this analyzer is to identify the normal patient, with all normal system-generated parameters, and to flag or identify patient results that require additional studies.**
- **Store and use the reagents as instructed by instructions for use of the reagents**
- **When you have changed the diluent, rinse or lyse, run a background to ensure that the system is primed immediately prior to running any samples.**
- **Pay attention to and record the expiration date and open-container stability of all the reagents. Be sure not to use expired reagents**
- **Keep the reagents still for a while before using them.**
- **Be sure the analyzer is off before switching on the power.**
- **Be sure to retain the shipping carton and all the packing materials, as they can be used for packaging if analyzer must be reshipped.**
- **Be sure to place the analyzer on a countertop.**
- **Be sure to sue the manufacturer-specified reagents, controls and calibrators.**
- **After connecting the reagents, be sure to tighten the cap to prevent contamination.**
- **Pay attention to and record the expiration dates and open-container stability days of all the reagents. Be sure not to use expired reagents**
- **For any reagent, the entered expiration date should be either the expiration date printed on the labeling or the open-container expiration date, whichever is earlier. The open-container expiration date is calculated as follows: the date that container is opened + the open-container stability days.**
- **For the whole blood samples to be used for WBC differential or PLT count, you shall store them at the room temperature and run them within 8 hours after collection.**
- **Be sure to use clean K_2EDTA anticoagulant collection tubes, fused silica glass/plastic test tubes and 20μL borosilicate glass capillary tubes.**

- **If you do not need the PLT, MCV and WBC differential results, you can store the samples in a refrigerator (2℃ - 8℃) for 24 hours. You need to warm the refrigerated samples at room temperature for at least 30 minutes before running them.**
- **Be sure to mix any sample that has been prepared for a while before running it.**
- **Be sure to keep dust from the prepared diluent.**
- **After mixing the capillary sample with the diluent, be sure to wait 3 minutes before running the sample. Be sure to run the prediluted samples within 30 minutes after the mixing.**
- **Be sure to evaluate predilute stability based on your laboratory's sample population and sample collection techniques or methods.**
- **Be sure to select proper reference range as instructed in Chapter 5.5 before running the samples. Otherwise, the obtained results may be erroneously flagged.**
- **When switching from the predilute mode to the whole blood mode, the analyzer will automatically wash the fluidic system.**
- **After entering all the desired information, you may press [F4] on the external keyboard to save the changes and exit to the "Count" screen.**
- **If you intend to do the background check instead of a patient sample, *ENTER* "0" into the "ID" box.**
- **Be sure to keep the sample probe tip away from the tube bottom, otherwise the aspiration volume may be inaccurate.**
- **If the analyzer detects WBC/RBC clogging or bubbles during the analysis, the corresponding error messages will be displayed in the upper left corner of the screen and the results of all the related parameters will be invalidated. See Chapter 11 Troubleshooting Your Analyzer for solutions.**
- **If the ambient temperature is outside the specified operating range, the analyzer will alarm you for abnormal ambient temperature and the analysis results may be unreliable. See Chapter 11 Troubleshooting Your Analyzer for solutions.**
- **The result of the background check will not be flagged.**
- **If the PLT value is less than 100×10^9 / L, it is recommended the result be verified by a microscope.**
- **To ensure the stability of the analyzer and the acuuracy of the results, be sure to do the Shutdwon procedure if your analyzer has been working for 24 consecutive hours.**
- **After entering all the desired information, you may press [F4] on the external keyboard to save the changes and exit to the "Sample (or Search) Histogram**

Review" screen.

- **Refer to the instructions of use of the control for information on the lot number, expiration date, open-vial stability days, expected results and limits.**
- **The entered expiration date should be either the expiration date printed on the labeling or the open-vial expiration date, whichever is earlier. The open-vial expiration date is calculated as follows: the date that vial is opened + the open-vial stability days.**
- **Be sure to use the manufacturer-specified controls. Using controls other than the specified will lead to misleading results.**
- **Refer to the instructions of use of the controls for how to store and use the controls.**
- **Be sure to calibrate your analyzer before trying to establish the expected results by calculating the averages of random patient samples.**
- **All of the measured parameters must be calibrated before readings of this analyzer can be used as valid analysis results.**
- **Refer to the instructions of use of the calibrator for information on the lot number, expiration date, open-vial stability days, expected results and limits.**
- **The entered expiration date should be either the expiration date printed on the labeling or the open-vial expiration date, whichever is earlier. The open-vial expiration date is calculated as follows: the date that vial is opened + the open-vial stability days.**
- **Be sure to use the manufacturer-specified calibrator. Using calibrators other than the specified will lead to misleading results.**
- **Refer to the instructions of use of the calibrator for how to store and use the calibrator.**
- **After mixing the calibrator with the diluent, be sure to wait 3 minutes before running it. Be sure to run the prediluted calibrator within 30 minutes after the mixing.**
- **Be sure to mix any prediluted calibrator that has been prepared for a while before running it.**
- **You should prepare 3 – 5 normal fresh blood samples for the calibration.**
- **If you press [MENU] to enter the system menu before the average is obtained at the "Calculate" screen, the next time you enter the "Auto-fresh blood" screen a message box will pop up to ask you whether to clear the data of the last calibration; If you press [MAIN] to exit to the "Count"screen before the average is obtained at the "Calculate" screen, the next time you enter the "Auto-fresh blood" screen a message box will pop up to ask you whether to clear the data of the last calibration.**
- **Probe cleanser is corrosisve. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when**

handling it in the laboratory.

- **Spills are possible during the soaking process. Keep a minimum 30cm distance from the analyzer.**
- **Before moving the analyzer, be sure to do the "Empty Tubing" procedure.**
- **Running sample with the background abnormal error present will lead to unreliable results.**
- **The troubleshooting chapter is not a complete service manual and is limited to problems that are readily diagnosed and/or corrected by the user of the analyzer. If the recommended solution fails to solve the problem, contact Mindray customer service department or your local distributor.**
- **Unless otherwise instructed, always turn off the power before trying to fix the error.**
- **Be sure to use the printer and scanner of the specified model only.**

C.5 Biohazard

- **Samples, controls, calibrators and waste are potentially infectious. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them in the laboratory.**
- **All the analyzer components and surfaces are potentially infectious, take proper protective measures for operation or maintenance.**

C.6 Abnormal Results

For your reference only.

C.6.1 Abnormal Sample Analysis Results

Parameter flags

If the analysis result is followed by an ”H” or “L”, it means the analysis result has exceeded the upper or lower limit of the reference range.

If you see *** as opposed to the result, it means the result is either unreliable or out of the operating range.

If the WBC result is less than 0.5×10^9/L, this analyzer will not perform the differential analysis and all the related parameter values will be non-numeric (***).

Histogram flags

The system will flag abnormal histograms.

- Abnormal WBC histograms will be flagged by one of the markings: R1，R2，R3，R4 and $R_{m.}$

R_1：indicates abnormality on the left side of the lymphocyte hump and possible presence of platelets coagulate, large platelet, nucleated red cell, insolvable red cell, protein, lipoid debris in sample, or electrical noise.
R_2: indicates abnormality between the lymphocyte hump and the mononuclear area and possible presence of atypical lymphocyte, original cell in the sample and increased eosinophil or increased basophil.
R_3：indicates abnormality between the mononuclear leukocyte and the neutrophilic granulocytes and possible presence of immature granulocytes, abnormal sub-population in the sample, or increased eosinophil.
R_4：indicates abnormality on the right side of the neutrophilic granulocytes hump and increased absolute number of neutrophilic granulocyte.
R_m：indicates at least two R flags.

- Abnormal PLT histograms will be flagged by one of the markings: P_m， P_S and $P_{L.}$

P_m：indicates blur demarcation between the platelet and red blood cell area and possible presence of large platelet, platelet coagulation, small red blood cell, cell debris or fibrin.
P_S：indicates excessive small PLTs.
P_L：indicates excessive large PLTs.

C.7 Abnormal QC Results

In case of any abnormal QC results, do the following steps until the problem is solved. If all the steps have failed, contanct Mindray customer service department or your local distributor for assistance.

- Check the upper left corner of the screen for error messages. Refer to Chaper 11 Troublshooting Your Analyzer for solutions to any displayed error messages;
- Check the L-J settings for inappropriate entries;
- Do the background check. In case of an abnormal background result, refer to Chaper 11 Troublshooting Your Analyzer for solutions.
- Re-run the control;
- Run another vial of control;
- Check if the analyzer needs to be calibrated.

D Communication

D.1 Introduction

The BC-3000 Plus can transmit the sample data and QC data to an external computer (a host) through its RS-232 serial port. The transmission can be conducted either automatically or through the command of the operator after the completion of the sample analysis. This section gives detailed discussion about the setup of transmission parameter, RS-232 serial port and the data transmission format, therefore, providing detailed information for the software engineers to program and for the user to conveniently perform transmission.

NOTE

- **When the communication symbol in the upper right corner of the screen appears animated, it indicates the communication is in process.**

D.2 Connection

The BC-3000 Plus can be connected with an external computer through a DB9 connector. The pins of the DB9 connector are shown in Figure12-1.

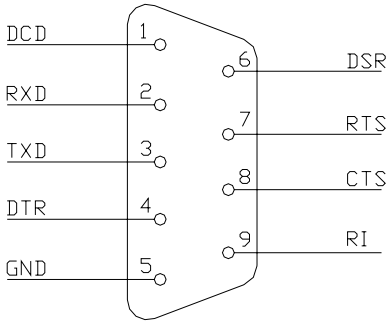

Figure12-1 DB9 connector

Pin description:
DCD：Carrier Detect
RXD：Receive Data
TXD：Transmit Data
DTR：Data Terminal Ready
GND：Signal Ground
DSR：Data Set Ready
RTS：Request to Send
CTS：Clear to Send
RI：Ring Indicator

The BC-3000 Plus communicates with a host through serial port 2, using Pin2, Pin 3 and Pin 5. The maximum transmission distance is 12 meters.

D.3 Transmission Data Format

D.3.1 Description

Symbols

[ENQ]	0x05
[STX]	0x02
[EOT]	0x04
[EOF]	0x1A
[ETX]	0x03
[ACK]	0x06
[NACK]	0x15
"A"	0x41
"B"	0x42
"C"	0x43
"#"	0x30-0x39
"*"	0x2A

If the Lot No., Month, Day, Year are empty in QC Edit menu, the “*” (2A Hex) will be transmitted to the host.

For all the data formats, if the data are marked “*”, then “*” (2A Hex) will be transmitted to the host.

L1 Region - L8 Region are LI - L8 of eight histogram discriminators as shown in Figure-12-2.

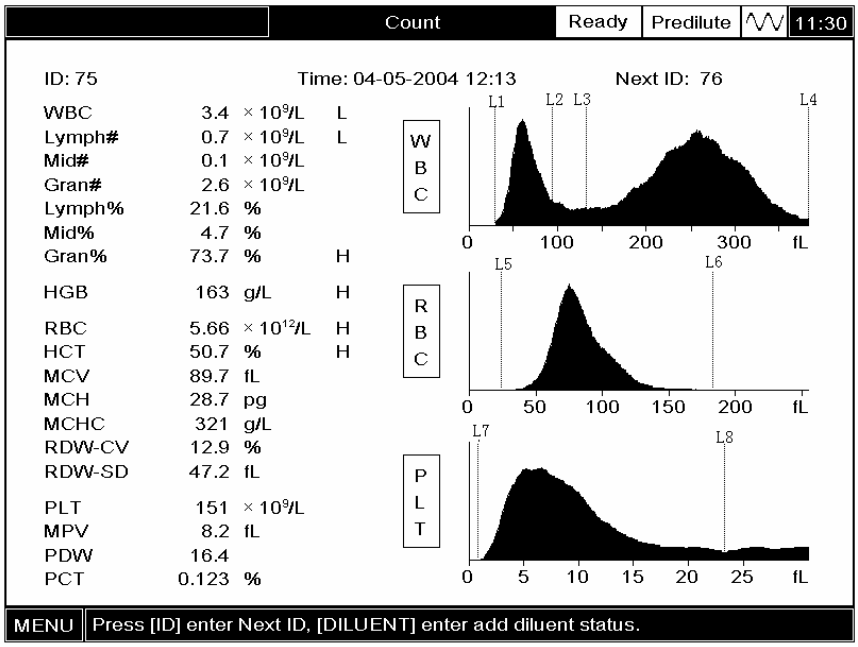

Figure12-2 L1- L8 demonstration

Programming

If the Handshake is off, BC-3000 Plus will transmit the body of the text without acknowledging the presence of an external computer.

If the Handshake is on, BC-3000 Plus will communicate with the external computer in following procedures:

1. BC-3000 Plus sends an ENQ (05 Hex), then waits up to 4 seconds for the external computer to respond. If the external computer does not respond, then one more ENQ (05 Hex) is tried. If it fails again, the analyzer aborts the transmission and reports a transmission error;
2. The external computer must respond by sending an ACK (06 Hex). If any other response is received, another ENQ (05 Hex) will be sent by the analyzer (maximum two ENQ [05 Hex] will be sent);
3. The analyzer then sends：

Body of text
EOT (04 Hex)
ETX (03 Hex)

4. Disconnection.

BC-3000 Plus sends an ETX 03 Hex), then waits 4 seconds for the external computer to respond. If no response is received, one more ETX (03 Hex) is sent, BC-3000 Plus waits 4 seconds before giving up and gives alarm of communication error.

If the external compute responds ACK, the transmission is done successfully. If the external computer responds NACK（15 Hex）, the analyzer repeat the transmission from step 3. If the received response from the computer is neither ACK（06 Hex） nor NACK（15 Hex）, the analyzer sends ETX(03 Hex) again.

D.3.2 Sample Data Format

If handshake is enabled	[ENQ]
If handshake is disabled	[STX]
Body of the text start	
Text Identifier	“A”
Version	##
ID length	###
The number of parameters	###
Number of the parameters having format descriptions	##
ID	##########
Sample Mode	#
Month	##
Day	##
Year	####
Hour	##
Minutes	##
Seconds	##
WBC[10^9/L]	###.#
Lymph#[10^9/L]	###.#
Mid#[10^9/L]	###.#
Gran#[10^9/L]	###.#
Lymph%[%]	##.#
Mid%[%]	##.#
Gran%[%]	##.#
RBC[10^{12}/L]	##.#
HGB[g/L]	###
MCHC[g/L]	####
MCV[fL]	###.#
MCH [pg]	###.#
RDW-CV[%]	##.#
HCT[%]	##.#
PLT[10^9/L]	####
MPV[fL]	##.#
PDW	##.#
PCT[%]	.###

RDW-SD[fL]	###.#
Reserved	############
Rm	#
R1	#
R2	#
R3	#
R4	#
Pm	#
Ps	#
Pl	#
L1 Region	###
L2 Region	###
L3 Region	###
L4 Region	###
L5 Region	###
L6 Region	###
L7 Region	###
L8 Region	###
Reserved	################
WBC Histo (256 channels)	###
RBC Histo (256 channels)	###
PLT Histo (256 channels)	###
Body of the text end	
If handshake is enabled	[EOT]
If handshake is disabled	[EOF]

D.3.3 Standard L-J QC Data Format

If handshake is enabled	[ENQ]
If handshake is disabled	[STX]
Body of the text start	
Text Identifier	“B”
File No.	#
Lot No.	######
Month	##
Day	##
Year	####
WBC[10^9/L]	###.#
RBC[10^{12}/L]	#.##
HGB[g/L]	###
PLT[10^9 /L]	####
Lymph#[10^9/L]	###.#
Lymph%[%]	##.#

Gran#[10^9/L]	###.#
Gran%[%]	##.#
HCT[%]	##.#
MCV[fL]	###.#
MCH[pg]	###.#
MCHC[g/L]	####
WBC Limit[10^9/L]	###.#
RBC Limit[10^{12}/L]	#.##
HGB Limit[g/L]	###
PLT Limit[10^9/L]	####
Lymph# Limit[10^9/L]	###.#
Lymph% Limit[%]	##.#
Gran# Limit[10^9/L]	###.#
Gran% Limit[%]	##.#
HCT Limit[%]	##.#
MCV Limit[fL]	###.#
MCH Limit[pg]	###.#
MCHC Limit[g/L]	####
Body of the text end	
If handshake is enabled	[EOT]
If handshake is disabled	[EOF]
If handshake is enabled	[ETX]

D.3.4 Run L-J QC Data Format

If handshake is enabled	[ENQ]
If handshake is disabled	[STX]
Body of the text start	
Text Identifier	‘C’
Month	##
Day	##
Year	####
Hour	##
Minutes	##
WBC[10^9/L]	###.#
RBC[10^{12}/L]	#.##
HGB[g/L]	###
PLT[10^9/L]	####
Lymph#[10^9/L]	###.#
Lymph%[%]	##.#
Gran#[10^9/L]	###.#
Gran%[%]	##.#
HCT[%]	##.#

MCV[fL]	###.#
MCH[pg]	###.#
MCHC[g/L]	####
Body of the text end	
If handshake is enabled	[EOT]
If handshake is disabled	[EOF]
If handshake is enabled	[ETX]

D.4 Transmission

D.4.1 Defining Transmission Settings

The data format is fixed for the transmission so that every byte to be transmitted has 7 data bits and 1 stop bit. Enter "**Setup → Transmission**" screen and edit the communication settings as instructed by **Chapter 5.6.**

D.4.2 Transmission at Count Screen

If the auto transmission function is on, once the analysis is done, the analyzer will automatically transmit the results to the external computer. If the auto transmission function is off, you can only transmit the results manually at the ***Review*** screen.

D.4.3 Transmission at Review Screen

Select the results you want to transmit and transmit them to the external computer as instructed by **Chapter 7.2.1.** .

D.4.4 Transmission at L-J QC Table Screen

Transmit the results as instructed by **Chapter 8.2.3**.

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